UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
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TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICALS INDUSTRIES LTD., TEVA NEUROSCIENCE, INC. and YEDA RESEARCH AND DEVELOPMENT CO. LTD.,

Plaintiffs,

v. 08-CV-7611 (BSJ)

SANDOZ, INC., SANDOZ INTERNATIONAL GMBH, NOVARTIS AG, and MOMENTA PHARMACEUTICALS, INC.,

Defendants.

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TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICALS INDUSTRIES LTD., TEVA NEUROSCIENCE, INC. and YEDA RESEARCH AND DEVELOPMENT CO. LTD.,

Plaintiffs,

v. 09-CV-8824 (BSJ)

MYLAN PHARMACEUTICALS INC., MYLAN INC., NATCO PHARMA LTD.,

Defendants. Non-Jury Trial

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New York, N.Y.
September 13, 2011
9:30 a.m.

Before:

HON. BARBARA S. JONES,

District Judge

APPEARANCES

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DAVID JONES, ESQ.

ALSO PRESENT: CORT CHASE, Litigation Support

THE DEPUTY CLERK: All rise.

THE COURT: Please be seated.

All right. I just wanted to say I did receive the designations, so thank you.

And, Ms. Holland?

MS. HOLLAND: Yes, your Honor. I think what we're going to do is just formally move those into evidence before we rest.

THE COURT: Okay.

MS. HOLLAND: Mr. Bennett will explain there's some issues with a couple of the exhibits that we're still working out.

THE COURT: All right, Mr. Bennett. Good morning again.

MR. BENNETT: Good morning, your Honor. So, first of all, we're going to move formally into evidence the clip reports form the depositions that we provided yesterday. First would be the Court Reporter --

THE COURT: You know, I have an idea. Are they all listed their?

MR. BENNETT: We do have a list, your Honor, that we could cleanup and give -- hand up.

THE COURT: Why don't we mark that as an exhibit, give it to the Reporter.

MR. BENNETT: That's fine.

THE COURT: Then we don't have to put it on the record.

MR. BENNETT: Okay.

THE COURT: That's, I assume, agreeable to defendants?

MR. DOYLE: It is, your Honor with the proviso, as Mr. Bennett said, there is a couple of exhibits to the depositions that are still being worked out as far as whether there's a foundation for them.

THE COURT: Okay, all right. Well, I'm admitting whatever ends up on that list, and if there are disputes, you'll bring them to me, I'm sure. Okay?

MR. DOYLE: Yes, your Honor. Thank you.

THE COURT: Great.

MS. BLOODWORTH: Then, your Honor --

THE COURT: We'll, they'll be listed as an exhibit and that way we're done.

MS. BLOODWORTH: Your Honor, if I may suggest. We should -- can we break out the exhibits we're going to move into your Honor as well as next to that list, the public --

THE COURT: I'm sorry, I didn't hear the first part, Ms. Bloodworth.

MS. BLOODWORTH: Should we also break out the exhibits that we'll move into evidence, and then also whether or not it has a publicly available version to it?

THE COURT: You mean with respect to the designations?

MS. BLOODWORTH: Yes, your Honor.

THE COURT: You're giving me unredacted, correct?

MS. BLOODWORTH: Correct.

THE COURT: And I think the list should just indicate that there's also a redacted version, that's all.

MS. BLOODWORTH: Yes, your Honor.

THE COURT: Okay. Anything else? Why don't we give it a number so I can admit it.

MR. BENNETT: Okay. I think there will be two lists, your Honor.

THE COURT: Okay.

MR. BENNETT: One will be the list of designations and associated video, and that will be PTX-977.

THE COURT: All right.

MR. BENNETT: And then also together a list of all the exhibits that are associated with the designation, that would be PTX-978.

THE COURT: All right, they're both admitted.

(Plaintiff's Exhibits 977 and 978 received in evidence)

THE COURT: And while I'm thinking of it, I believe in the first trial on inequitable conduct, we instituted the practice that counsel would review the transcripts as they were received and forward agreed upon corrections to our court reporters. So I'm hoping that that same practice is being

followed in this case.

MR. BENNETT: Yes, it is.

THE COURT: Okay, great.

All right, anything else?

MS. HOLLAND: No, your Honor. So with those deposition clips and exhibits, associated exhibits coming into evidence, plaintiffs rest their case.

THE COURT: All right. Who goes -- who is going first, Ms. Bloodworth?

MS. BLOODWORTH: Yes, your Honor.

THE COURT: For Mylan?

MS. BLOODWORTH: Yes, your Honor. Mylan would like to call Dr. Walter Owens.

THE COURT: Mr. Bennett?

MR. BENNETT: I suppose I should have mentioned this a few seconds ago, but Mylan identified a couple of documents that they may use with Dr. Owens that were produced recently, and were produced after the close of discovery; specifically, an FDA submission, your Honor, as well as a slide show. And I I'm not sure if counsel is still planning on using those with Dr. Owens. But if Mylan is going to use those with Dr. Owens, we would object, given that they were produced after the close of discovery. We've had no opportunity to depose any of the fact witnesses about those documents, and we received no notice from Mylan as to the relevance of those documents to any issue

in the case.

THE COURT: Ms. Bloodworth -- well, can you identify the documents we're talking about?

MS. BLOODWORTH: I think, your Honor, what, and Mr. Bennett will correct me if I'm wrong, is discussing our -- Mylan submitted amendments to its ANDA in April of 2011. We actually submitted it on April 19th. We provided that amendment to plaintiffs on April 21st. Plaintiff's last expert report in this case was served on I believe May 29th, 2011, and plaintiffs never asked for any additional discovery from Mylan on these amendments.

THE COURT: Mr. Bennett?

MR. BENNETT: Well, the expert reports that Ms. Bloodworth is referring to were the reports that were put in with respect to Sandoz's supplemental claim construction, your Honor. And she's -- Ms. Bloodworth is right, that we have -- those were the last reports that were submitted in the case.

That being said, there's been pending contention interrogatories upon Mylan throughout the entire case. These documents were produced to us -- in one case this presentation that was made to the FDA was done in August, just this past August, was produced to us just a few weeks ago.

THE COURT: So there's a presentation to the FDA that relates to the April 19 ANDA?

MS. BLOODWORTH: Yes, your Honor.

THE COURT: And that was done in August?

MS. BLOODWORTH: Yes, your Honor. And we provided that under the parties' agreement to produce that information.

MR. BENNETT: The problem here, your Honor, is that despite the contention interrogatories that have been pending upon Mylan throughout the case, there's been no identification whatsoever that these document are relevant to an issue in the case. And they were produced to us after the close of discovery, so we had no opportunity to depose a fact witness. There's been no mention of these documents in their expert reports either, which were --

THE COURT: Well --

MS. BLOODWORTH: Your Honor --

THE COURT: -- the ANDA itself you've had since April 19, right. But you didn't -- there was no indication from Ms. Bloodworth for Mylan that their was anything in it that was relevant, is that what you're saying?

MR. BENNETT: Correct.

MS. BLOODWORTH: Your Honor, if I may also add. After the call with your Honor on the Sandoz extra discovery issue, I believe we had that in late August. I was surprised to hear plaintiffs asking for additional fact discovery from Sandoz based on a major amendment in the Sandoz case. So I actually called Ms. Holland and asked her whether or not they were going to be seeking any additional discovery of Mylan based on our

amendments. And we had an e-mail, you know, e-mail exchange, whereby plaintiffs said they were going to rest on their expert reports that they put in as of, you know, on the ANDA as it was without the amendment. Those reports aren't our current amendment.

THE COURT: I'm sorry?

MS. BLOODWORTH: Those expert reports are not our current ANDA. That major amendments to our ANDA was our changes to our entire, you now, most of our characterizations of our drug product and drug substance sections.

THE COURT: So now you're telling me that like Sandoz, you've made a major amendment to your ANDA?

MS. BLOODWORTH: We made an amendment to the ANDA in April of 2011, yes, your Honor. And that amendment -- particularly, we actually briefed this amendment in the Gad case, the second case. We filed a supplemental motion to dismiss based on this amendment. Plaintiffs briefed it. Plaintiffs relied on the amendments in their reply expert report for Dr. Dubin that was served on May 29th, 2011, under the Sandoz claim construction infringement report that they served on Mylan. And then I called and asked Ms. Holland if they were planning on seeking any additional discovery, and the answer was no.

It's, you know, I think I provided every opportunity and did everything I could to make sure that plaintiffs had the

information to determine what case they would like to put on against Mylan.

MS. HOLLAND: If I may, your Honor. We did Ms. Bloodworth and I did have an e-mail correspondence on this.

As far as we can tell from the amendment, what was briefed in Dr. Dubin's report or, I'm sorry, Dr. Dubin gave opinions on his report was what seemed to us to be relevant to the case at hand.

If Ms. Bloodworth now is saying that there is a whole bunch of other stuff that's relevant to this case, we just didn't have notice of that. We can't take a deposition now at the 11th hour on what might be issues related to the case if we can't tell that they are based on the submission. We didn't get any indication from Ms. Bloodworth that she was using a particular document to support a particular position in this litigation.

MS. BLOODWORTH: Your Honor, what Dr. Owens is here to testify to about today is what is currently in Mylan's ANDA, what is currently in Mylan's ANDA and what Mylan uses to characterize its product in its UC markers. Plaintiffs have known about that, we informed your Honor about that. In the Gad case, we briefed it. Plaintiffs relied upon it in their reply expert report of Dr. Dubin, and I don't see how there possibly would be any surprise that the issue here is whether Mylan ANDA versus the asserted claims.

MS. HOLLAND: The issue, your Honor, is something that Mr. Owens is going to say on the stand. Is that going to be about this new amendment? Is that going to be used in some way to support a defense in a way that we don't have notice of? That's the real issue.

THE COURT: Why don't you tell us, Ms. Bloodworth. I guess no one can object to is it Dr. Owens or Mr --

MS. BLOODWORTH: It's Dr. Owens.

THE COURT: Dr. Owens telling us what's in the ANDA, but what are you going to argue from it, just tell us.

MS. BLOODWORTH: I think we would argue that plaintiff's evidence on the 2 to 20 claims based on Dr. Grant's testing, which he said was based on evidence and documents, specifically data that was generated from Mylan's data, he said it was accurate and correct because of what Mylan did for it. And the fact of the matter is first of all that's not how Mylan used that data, and second of all, it's no longer data that's part of our ANDA.

MS. HOLLAND: Your Honor, this is the first we are hearing about this, literally the first time we're hearing about this. Dr. Grant put in expert reports, he got on the stand. He testified about the data that Mylan provided to the FDA. That was the basis of his opinions on those molar fraction claims, and now we're hearing basically that Mylan is saying oh forget about all that, because we have some new data

they we gave the FDA you.

MS. BLOODWORTH: Your Honor, that's why I e-mailed Ms. Holland.

MS. HOLLAND: No expert --

THE COURT: One at a time, please.

MS. BLOODWORTH: I was so surprised that Teva was seeking additional discovery based on a Sandoz amendment on a key issue in the case and they didn't seek any corresponding discovery from Mylan, when they had our information for months and we're actually still in phase where we were performing expert discovery.

There is no doubt that Dr. Grant, through Teva's counsel, could have had access to this amendment. We provided it on April 19th to the FDA. We immediately provided it on Monday, April 21st, to Teva. Dr. Grant submitted his last report months later. Actually, Teva asked us for underlying factual information, SEC data, which we provided to them. And I can't make them file an expert report against me. All I can do is call and ensure that they're going to rest on the opinions that they had in their expert reports, and they're not going to amend and they only want to seek any additional discovery based on all the information that we had given them. And I specifically referenced to Ms. Holland the fact that we had submitted this amendment and provided it to them in April.

MS. HOLLAND: Your Honor --

THE COURT: All right.

MS. HOLLAND: -- is Ms. Bloodworth now saying that the information that Mylan gave to the FDA in this ANDA is no longer accurate, is that what you're saying, Ms. Bloodworth?

MS. BLOODWORTH: I'm saying it's completely different.

MS. HOLLAND: Is it accurate or not accurate?

THE COURT: I'm. The current ANDA --

MS. BLOODWORTH: The current --

THE COURT: -- is what we're talking about --

MS. BLOODWORTH: The current ANDA --

THE COURT: -- from April 19th.

MS. BLOODWORTH: -- from April 19th has a series of markers in its ANDA to characterize its distribution. Those markers range from 420 to 77,750. The old markers ranged from 3,000 to 9,000. Mylan didn't feel that was sufficient. They had been continuing and had -- Teva took a lot of information and discovery on Mylan's attempt to change between universal calibration system. For this reason they deposed Dr. Owens on it, they deposed many of our witnesses on it. They knew it was coming. And they knew why we were doing it. And then we did it in April. And we provided them with the information. They asked for additional underlying data, we provided them with that, and they still never supplemented their expert report.

MS. HOLLAND: We had no idea that there was a contention that Dr. Grant's opinions would be insufficient

because he didn't rely on the molar fraction data from this new submission in April. In order for Ms. Bloodworth to be making that argument, she has to be saying that they submitted, what Mylan submitted to the FDA in its original ANDA was not accurate data, because if it was accurate data, then Dr. Grant's opinions are fine no matter what the later calibration shows.

MS. BLOODWORTH: What Mylan -- and Dr. Owens is obviously in a better position to explain this than I am. But my understanding is Mylan did not rely on that data to do what Dr. Grant did with it, first of all.

I took Dr. Winter's deposition. This was made very clear that he didn't look at the calibration data, he was told not to look at the calibration data. I questioned Dr. Grant on the calibration data and that was -- it was never the purpose that Mylan was going use it for. But they did want to do it, they did want to have a full characterization of the distribution, and that's why they were working on this universal calibration system. They worked on it from 2009, all the way up to 2011 when they submitted the amendment. They asked for the data underlying it. We gave them the data. That's a discovery request, your Honor. We provided that data underlying universal calibration amendment. And plaintiffs, despite raising a big fuss against Sandoz, never made any request of us. So I called and said --

THE COURT: Okay.

MS. BLOODWORTH: -- I mean --

THE COURT: Okay. We'll hear Dr. Owens' direct testimony, and then if Teva wants an adjournment to take his deposition and the opportunity to do rebuttal, I'll grant it.

MS. HOLLAND: Thank you, your Honor.

MS. BLOODWORTH: Thank you, your Honor.

THE COURT: Are there other witnesses today besides Dr. Owens?

MS. BLOODWORTH: There are other witnesses, but just -- I think Doctor -- I think Mr. Bennett raised a second document which was an FDA presentation that --

THE COURT: Yes.

MS. BLOODWORTH: -- goes to this amendment. Again, Dr. Owens --

THE COURT: Might as well see it.

MS. BLOODWORTH: He's just going to say what he said at the FDA.

THE COURT: Okay.

MS. BLOODWORTH: Thank you, your Honor.

THE COURT: Very good. Come on up, Doctor.

WALTER H. OWENS,

called as a witness by the defendant,

having been duly sworn, testified as follows:

DIRECT EXAMINATION

BY MS. BLOODWORTH:

Q. Good morning, Dr. Owens.

A. Good morning.

Q. Can you please state your full name for the record?

A. Walter H. Owens.

Q. And where do you currently reside?

A. I currently reside in Morgantown, West Virginia.

Q. And where are you currently employed?

A. I am currently employed with Mylan, Incorporated.

Q. And what is your current position with Mylan, Incorporated?

A. I currently hold the position of vice-president of Global R&D for finished dosage form development.

Q. Can you briefly describe your duties as vice-president of global R&D?

A. I can. The responsibilities include oversight of all of our global R&D centers for the development of finished dosage forms that ultimately get administered to patients.

Q. What is a finished dosage form?

A. It's actually a pharmaceutical product. It's the final product that you or I would receive as a patient from either a doctor or an institution.

Q. And where are the R&D located in?

A. We have multiple R&D centers. We have an R&D center in Morgantown, West Virginia, we also have a R&D center in Hataba, India, Tokyo, Japan, we have two centers in Ireland, one in New

Jersey, and then two tech transfer centers, one's in Australia and one in Ireland as well.

Q. When did you join Mylan?

A. I joined Mylan in May of 1994.

Q. And have you been employed at Mylan throughout this time?

A. I have.

Q. Can you please briefly describe the nature of Mylan's business?

A. Mylan is a leading generic and specially pharmaceutical company serving approximately 150 countries worldwide.

Q. And when you joined Mylan in 1994, was it known as Mylan, Inc.?

A. When I joined Mylan in 1994, it was not.

Q. What was it then known as?

A. It was Mylan Laboratories, Incorporated.

Q. And did you work for Mylan Laboratories, Incorporated?

A. I did not. I actually worked for Mylan Pharmaceuticals, Incorporated at that time.

Q. And what is Mylan Pharmaceuticals?

A. Mylan Pharmaceuticals is a subsidiary of Mylan, Incorporated. It's responsible for the U.S. commercial and manufacturing business.

Q. And in your role as vice-president for global R&D, how many people do you supervise?

A. There are approximately 1,000 employees in our global R&D

organization.
Q. Does Mylan have any subsidiary that produces branded pharmaceutical products?
A. We do. Dey Pharma is a branded pharmaceutical group that specializes in asthma and allergy treatments, most notably the epinephrine injector pen.
Q. And, approximately, how many products does Mylan and its subsidiary manufacture?
A. We have approximately a thousand products, separate products worldwide.
Q. And how long have you been the president or, excuse me, the vice-president for global R&D?
A. At this point in time, about two and a half years.
Q. And could you briefly describe your positions prior to becoming the vice-president of global R&D?
A. I can. Prior to becoming vice-president for global R&D, I held the position for vice-president for R&D of North America, focusing on the development of solid oral dosage forms for that particular marketplace.

Prior to that position, I was the vice-president for R&D chemistry, which had oversight for analytical chemistry development, as well as bio-analytical chemistry development, and then I've held various R&D and quality positions within the Mylan organization since May of '94.
Q. Can you briefly describe your educational background?

A. I can. I received a bachelor of science degree in chemistry in Purdue University in 1987; subsequently attended West Virginia University and received a Ph.D. in physical organic chemistry, and then attended Rice University where I performed post doctoral research on the area of chemical physics and physical organic chemistry.
Q. And, Dr. Owens, you're aware that Mylan has filed an Abbreviated New Drug Application for FDA approval for glatiramer acetate, correct?
A. I am.
Q. Does my Mylan have a partner for this project?
A. Mylan does have a partner for the program.
Q. Who is that partner?
A. That partner would be Natco Pharma, Limited.
Q. And what is the relationship currently between Natco Pharma and Mylan?
A. It is a partnership that developed glatiramer acetate for the United States market, Natco Pharma being responsible for supply of the active pharmaceutical ingredient, and Mylan being responsible for characterization of that active pharmaceutical ingredient compared to the reference drug Copaxone.
Q. And why did Mylan enter into this agreement with Natco to develop glatiramer acetate product?
A. It was a strategic move for Mylan. This product gave us an opportunity to broaden our dosage form platforms into

injectable products, it represented a complex molecule for us to leverage our technology platform, and also learning to move forward into the biologic products regime.

Q. And when did you enter into the agreement with Natco?

A. In 2008.

Q. Did you know when the Mylan ANDA was originally filed?

A. Mylan ANDA would have been filed in June of 2009.

Q. And did you have any responsibilities with respect to the glatiramer acetate project?

A. I did.

Q. And can you briefly describe those responsibilities?

A. The groups that I have responsibility for would have been associated with the characterization of the Natco material or the Mylan glatiramer acetate in comparison to the Copaxone finished product.

Q. And what you have had received, what were they specifically looking at with respect to the ANDA?

A. There was real a very broad range of technology that those groups would have been utilizing and examining. That ranged from typical analytical chemistry techniques, as well as biological characterization, and even immunological characterization.

Q. When Mylan filed its ANDA in June of 2009, what was it demonstrating scientifically to the FDA?

A. What Mylan was demonstrating is that the Mylan glatiramer

acetate material was equivalent to the referenced product Copaxone.

Q. And how did Mylan go about this?

A. Again, Mylan went about this by characterizing and comparing the Mylan glatiramer acetate under that very broad battery of tests that I mentioned, against Copaxone as a direct comparison head to head.

Q. And was molecular weight distribution one of the properties that Mylan looked at to show the -- was molecular weight distribution one of the properties that Mylan looked at to show equivalence with Copaxone?

A. Molecular weight and molecular weight distribution would have been examined as part of this characterization.

Q. Why?

A. As a generic, our responsibility is to demonstrate sameness to the referenced product Copaxone. In this particular case the Copaxone labeling requires that the molecular weight be between 5,000 and 9,000 daltons. So, therefore, molecular weight becomes a critical parameter that we must assure falls within that range as equivalent to that of Copaxone.

Q. And, Dr. Owens, I believe you have a binder in front of you. Could you please turn to PTX-318R. Do you recognize this document?

A. I do recognize this document.

Q. And what is this document?

A. This document is part of the Mylan ANDA. It's States actually the request for waiver of in vivo studies.

MS. BLOODWORTH: And, your Honor, I believe PTX-318 is already in evidence. We move for its admission?

THE COURT: Any objection?

MR. BENNETT: No objection, your Honor.

THE COURT: All right.

(Defendant's Exhibit 318 received in evidence)

Q. If you can turn Honor to the page ending in 112?

A. I have that page.

Q. Can you please explain what is shown in table three?

A. I can. Table three is actually a listing of polypeptide reference standards that were used in Mylan's original ANDA for size exclusion chromatography calibration.

And what is provided in this particular table is really three columns; the standard with these numbers that are MWS, followed by numerical value. That's merely a designation of a standard. That's a bit of a nomenclature to keep track of the standard.

Followed by that is the actual amino acid sequence of those particular peptide standards.

And then finally the last column represents the molecular weight in daltons for each of the individual peptide standards. And as you can see here, it ranges from 3,757 daltons up to the last MWS-86, standard which is 9220 daltons.

Q. Thank you, Doctor. If you could please turn in your binder to PTX-325-R?
A. Could you give me the number again, please?
Q. Sure. It's 325-R.
A. I have it.
Q. Do you recognize this document?
A. I do.
Q. Can you please turn to the page ending in 1057. Can you please explain what's on this page?
A. I can. Actually the numbers are a little hard to see on the bottom of that screen, but for the --
THE COURT: Excuse me. This was also admitted previously?
MS. BLOODWORTH: Yes, your Honor.
THE COURT: Okay. Go ahead. Sorry, Doctor.
A. Thank you, your Honor.
The graph in the center of the page is important. What this is is the calibration curve utilizing the polypeptide standards that we had just previously referenced in the prior exhibit, and the squares that you see in the center of that graph are each of those individual polypeptide reference standards. That is a function of retention time, the size exclusion chromatography.
Q. And why were these standards chosen?
A. These particular standards were chosen at the time because

they bracketed the labeled range of molecular weight, especially peak molecular weight that we were trying to achieve to meet that labeling requirement that we have for the referenced product Copaxone. So the standards actually fall between approximately 3,700 daltons up to 9,220 daltons compared with the label range of 5,000 to 9,000 daltons.

Q. Were these standard, or were these markers or standards relied upon to generate any data to meet a release specification, other than the Mp molecular weight specification?

A. These particular set of reference standards would have only be used to generate the Mp molecular weight value and were not relied upon for any other release specifications.

Q. Mylan also reported MW and MN values using these standards, is that correct?

A. That's correct.

Q. Did you rely on your MW and MN determinations when releasing your -- when setting your specifications?

A. Again, those values were not proposed as a release specification within the original ANDA.

Q. And does Mylan still rely on these narrow polypeptide standards today?

A. Mylan does not.

Q. What does Mylan rely upon today?

A. Mylan has updated this methodology to utilize a universal

calibration that relies upon PEG and PEO reference standards.
Q. And why did Mylan make this switch?
A. The switch is fundamentally made for two reasons. The first being that these particular polypeptide reference standards -- and I believe you saw on the last exhibit were sourced from China, from a third party, we felt that utilizing that particular source in the long term fashion would be difficult. And, in addition, the narrow range in the polypeptide reference standards that were used here originally did not provide us broad coverage or broad evaluation of the entire glatiramer acetate molecular weight distribution. So we wanted to more fully characterize that distribution in a more accurate fashion. So, therefore, work was done to move towards a universal calibration.
Q. When did Mylan begin working on a method to develop the universal calibration system?
A. That work would have been initiated in late 2009.
Q. And when did Mylan amend the ANDA to include the universal calibration method?
A. That amendment was made to FDA in April of 2011.
Q. If you could please turn in your binder to DTX-1411. Do you recognize this document?
A. You do.
Q. If I can draw your attention to the third page of the document ending in 467. What is this document?

A. This would be the eCTD transmission of the amendments that Mylan had made to FDA.
Q. And what type of submission was this?
A. As indicated in the right-hand corner of this eCTD header it says submission type, and it was considered an amendment.
Q. And can you please explain what sections of the ANDA were revised in this amendment?
A. The section of the ANDA that were revised were associated with drug substance, as well as drug product specifications and test methodology related to universal calibration use.
Q. And if you could, please, turn to the Bates, the number ending in 491. What is shown on this page?
A. On this particular page, focusing on the upper half of the page, what you have is a data set comparing three lots of Mylan's product to that of Copaxone, with all the molecular weight premise shown. This was performed by universal calibration. And then in the middle of the page you can see all of the areas of the ANDA that would be impacted by this particular analytical methodology change. So the drug substance specifications would have been changed, the drug substance molecular weight by SEC with the universal calibration test procedure has now been included, new certificates of analysis, as well as finished products specifications, the finished product drug test procedure for SEC, and even the post prestability protocols that were called

for this SEC test to be utilized.

So, fundamentally, the universal calibration has been incorporated now as the regulatory method of record throughout the entire ANDA.

Q. And that methodology replaces the narrow polypeptides standards that were in the original ANDA?

A. That methodology does indeed replace the narrow range of polypeptide standards that were in the original ANDA.

Q. And did you have any meetings with the FDA to discuss this amendment?

A. We did have a meeting with FDA.

Q. Did you attend that meeting?

A. I did attend that meeting.

Q. Did you prepare any materials to show to the FDA during that meeting?

A. We did prepare a presentation for FDA.

Q. If you could turn in your binder to DTX-2046. Do you recognize this document?

A. I do.

Q. And did you make this presentation to the FDA?

A. I did make this presentation to FDA.

Q. If you could, please, turn to the page ending in Bates number 521. Do you have an understanding as to what is shown in these figures?

A. I do.

Q. What is shown in the top figure labeled original SEC level?
A. This would be an example of the original size exclusion chromatography method utilizing the polypeptide reference standards that we originally discussed.

What you can see in the size exclusion chromatogram, the dark black traces are representative of the narrow range of polypeptide reference standards that were used in the original ANDA. Then this has been overlaid with this red molecular weight distribution for WV-903, which is actually a finished product, Mylan finished product lot.

What you can see from that is that these polypeptide reference standards again provide a very narrow overlap with WV-903 that actually leave a fairly large portion of the molecular weight distribution untouched. And those particular reference standards don't do a good job of characterizing that molecular weight distribution in that particular area.
Q. And what is shown on the bottom graph?
A. The bottom graph is an example of our now improved and submitted to FDA size exclusion chromatography method utilizing universal calibration. And again these are PEGPEO reference standards. Again in black you see the reference standards themselves. They encompass a range of 420 daltons all the way through 77,350 daltons. And then these again are overlaid with the same finished product lot from Mylan, which is WV-903. And what you can see from this is that the methodology now uses

reference standards that can encompass the entire molecular weight distribution for Mylan's glatiramer acetate.

Q. Are these calibration markers now in the ANDA appropriate to calculate the MW. and MN values that go across the distribution?

MR. BENNETT: Objection, your Honor. Now we're veering into what seems like expert testimony from Dr. Owens.

THE COURT: I haven't heard any foundation with respect to this.

MS. BLOODWORTH: Okay.

Q. Dr. Owens, in your work with Mylan, do you routinely oversee the characterization work that's shown on these slides?

A. I have had oversight for the teams that perform the work that is represented in these slides.

Q. And was it a concern at Mylan or are you personally aware that there was a concern at Mylan that the full distribution was not covered by the former narrow polypeptide standards?

A. The narrow polypeptides standards did not cover that full distribution of molecular weight.

MS. BLOODWORTH: We can leave it that, your Honor.

THE COURT: You know, I think the objection is that this is expert testimony, correct?

MR. BENNETT: Yes, your Honor. Well, the previous question I think was trying to elicit expert opinion testimony.

THE COURT: Right. And I guess the only thing I don't

know is anything about Dr. Owens' background. I know what he does at Mylan. Maybe I missed it.

MS. BLOODWORTH: Yeah.

THE COURT: Early.

MS. BLOODWORTH: We weren't qualifying Dr. Owens as an expert, so we briefly just described his educational background.

THE COURT: Right.

MS. BLOODWORTH: He is just testifying as to what Mylan's impressions were and what Mylan's representations were to the FDA on this. I wasn't asking him to say what an expert --

THE COURT: So I'm not taking this for the truth, this is just what Mylan's representing?

MS. BLOODWORTH: I think this is the truth of what is Mylan's opinion on whether or not there, you know, whether or not their representations in their ANDA are complete and accurate.

MR. BENNETT: I think there is a problem there in terms of the offering of any opinions here, your Honor.

THE COURT: I mean I'll hear him out, but you have to understand that without qualifying him as an expert in the underlying methodology in what we're talking about here, okay, that's what Mylan says.

MS. BLOODWORTH: Yeah, your Honor, that's -- literally

the only point is that there is a narrow distribution that Mylan did not rely upon outside of the peak molecular weight and now there is a broader distribution that they do rely upon for the distribution.

THE COURT: All right, I'll listen. Go ahead.

MS. BLOODWORTH: Actually that was the last question on that topic.

Q. So let's turn to a new topic Dr. Owens.

THE COURT: Okay, all right.

Q. You're familiar with the process that's described in the ANDA, is that correct?

A. I am.

Q. Now going back in time to 2008 when Mylan partnered with Natco, was the glatiramer acetate synthetic process for the ANDA already finalized?

A. It was not.

Q. And what was the Mylan's role with respect to that synthetic process?

A. Mylan's role regarding the synthetic process was to actually provide characterization and analytical feedback to Natco in order for the ultimate goal being to demonstrate sameness and equivalence to the referenced product, Copaxone.

Q. And were you personally involved in that process?

A. Again, I had oversight for the teams at Mylan that were conducting the characterization efforts.

Q. And did you routinely participate in meetings and discussions with the scientists involved in those efforts?
A. I did.
Q. Were there multiple processes still being considered in 2008?
A. There would have been multiple synthetic processes under consideration in 2008.
Q. If we could please turn to PTX-262. Do you recognize this presentation?
A. I do.
Q. Did you prepare and present a portion of this presentation?
A. I recall having prepared and presented portions of this presentation.

MS. BLOODWORTH: Your Honor, we move for admission of PTX-262?

MR. BENNETT: No objection, your Honor.

THE COURT: Admitted.

(Plaintiff's Exhibit 262 received in evidence)

Q. What was the purpose of this meeting?
A. This meeting was update and overall summary presentation to our executive management regarding the synthesis and the preliminary characterization data that he had acquired regarding our glatiramer acetate and the referenced product Copaxone.
Q. Were there different synthetic processes considered at this

meeting?
A. I recall there being different synthetic processes under consideration at this meeting.
Q. Can you please turn to, in your binder, to page ending 891?
A. Can I have the page again, please?
Q. Sure. Ending in 891. Were these the three processes that were discussed during this meeting?
A. These were -- would be three processes that were under discussion at this meeting.
Q. And in point one it says, currently validated process. Is that the process that was considered to be the ANDA process in the fall of 2008?
A. That would not be the process that finally appears in the ANDA.
Q. Did that process change between the fall of 2008 and the filing of Mylan's ANDA?
A. It did.
Q. In general, how did it change?
A. Major change in this process was with regard to the debenzylation stage in the synthetic process whereby phenol was added.
Q. And why was this change made?
A. The change to add phenol to the synthesis in the debenzylation step was intended to reduce, if not eliminate the presence of bromotyrosine in the finished glatiramer acetate.

Q. And why did Mylan want to reduce or limit the presence of bromotyrosine?
A. We conducted some characterization work at Mylan using some original material that was provided by Natco, and compared that to Copaxone. And we identified that the Natco material contained levels of bromotyrosine, whereby the Copaxone product did not. So we viewed that as a significant difference and, therefore, made efforts to have this removed from the final synthesis.
Q. And how did you discover the bromotyrosine in the composition?
A. The bromotyrosine at this point in time was evaluated through proton MR spectroscopy.
Q. And if you could please turn in your binder to the pages ending in 913 through 18. Do you recognize these slides?
A. I do.
Q. Did you prepare these slides?
A. I have.
Q. And can you please explain to me the analysis that's shown on these slides?
A. I can. I'll probably go through page by page, if that's okay.
Q. Sure.
A. The first proton NMR spectrum that you see here is material that was isolated from a commercial lot of Copaxone. So it's

actually taken from the syringe as the title indicates.

And then we have a box that is drawn around the area, seven parts per million and the NMR spectrum. These two peaks are indicative of the tyrosine portion of the polypeptide composition. Again, this would be an NMR spectrum of Copaxone. So if you flip to the next slide. Now what we show is an NMR under the same set of conditions, material provided by Natco, and this was isolated actually from the vial as indicated in the header. And if you look at the same area around seven parts per million, you start to see the deviation, fairly substantial deviation in the NRM behavior in that region. Instead of seeing two distinct peaks, now you start to see other peaks that are growing in to this particular region. So this indicated a difference to us between Natco's material Copaxone at this time.

Q. What does the next slide show?

A. The next slide is actually computer simulation. So what we did is we have software available to us that allows NMR spectra to be predicted. And what we allow the computer to do is to predict the NMR spectrum for pure tyrosine. That's what this particular slide shows. So, again, when you're looking at seven part per million region, what you see is that the computer predicts two well defined peaks in that particular region for tyrosine.

Then if we move to the next slide.

Q. For the record you're on page ending 916, correct?
A. Move to the next slide. What we have now asked the computer to do is to simulate the NMR spectrum for mono-brominated tyrosine or bromotyrosine, and again examined that important region around seven parts per million. And what you see now is that you have differentiation -- it's no longer two peaks, but it's actually three peaks that show up on this particular region of the spectrum.
Q. And what did this conclude?
A. Well, it actually helps us evaluate the fact that tyrosine and bromotyrosine have a distinct NMR signature, and they can be differentiated. So if we were go to the next slide, I believe. What this particular slide -- again, a simulation -- shows is that if we take the two previous NMR spectrum, we overlay them, what would a product that has a mixture of tyrosine and bromotyrosine look like in the NMR in that region of seven parts per million. Now what you see is really the evolution of four distinct peaks that would be present if you had a mixture. And in the case the computer simulates a one-to-one mixture.
Then if we can go to the last slide I think that you mentioned
Q. Yes.
A. So now what we've done is we've taken the original Natco material that was provided to Mylan for characterization, and

we've overlaid that what the computer simulated NMR spectrum, now you can see start to see why the Natco material shows differences in the NMR around seven parts per million. It's actually demonstrating, you can even lineup the peaks and the small side peaks line for line with the computer simulation that actually shows a mixture of tyrosine and bromotyrosine being incorporated into the polymer.

Q. Now, what did this presence of bromotyrosine in the composition prompt Mylan to do?

A. Again, it prompted us to have Natco remove bromotyrosine from the molecule through its synthetic strategy.

Q. And was that accomplished?

A. That was ultimately accomplished.

Q. And how is that accomplished?

A. Natco utilized phenol in the debenzylation stage of its manufacturing process for the active pharmaceutical ingredient.

Q. Is that the process that's currently in the ANDA?

A. The process that contains phenol is currently in the ANDA.

Q. And if we can look at that synthetic process. You can turn to PTX-321R. Do you recognize this document?

A. I do.

MS. BLOODWORTH: Your Honor, this was previously admitted.

THE COURT: Thank you.

Q. What is 321, PTX321, Dr. Owens?

A. PTX 321 represents the schematic overview of the synthetic strategy that leads to the formation of the glatiramer acetate copolymer.
Q. And if you could turn to the page ending in 247. What is GMAF2 on the upper left-hand corner?
A. GMAF2 is a designation for the material that is the output of this debenzylation stage process, and so it would be the glatiramer acetate copolymer that contains a trifluoracetyl acetic acid protecting group, but it hasn't been debenzylated and depolymerized.
Q. And can you walk through this -- well, first let me ask you, is this sometimes referred to as the debenzylation step?
A. This particular stage of the process has been referenced to debenzylation step in the past.
Q. And how is it shown that the benzyl protecting group of the glutamic acid is removed?
A. What's shown here again this is schematically is that hydrobromic acid in a solvent or mixture of acetic acid is added to a reactor, phenol is then introduced, followed by the addition of GMAF1, which is the fully benzo protected polymer from the previous stage of synthesis, and then the reaction is carried for to yield a GMAF2 dibenzylated product.
Q. And so the current process does not contain the bromotyrosine in the composition, is that correct?
A. The output from the current process that's in the ANDA does

not contain bromotyrosine.

Q. Thank you, Dr. Owens.

MS. BLOODWORTH: I have no further questions.

THE COURT: All right. You want a few minutes, Ms. Holland?

MS. HOLLAND: Mr. Bennett is going to be doing the cross-examination.

THE COURT: I'm sorry. Mr. Bennett?

MR. BENNETT: Sorry, your Honor?

THE COURT: Did you want a few minutes?

MR. BENNETT: That would be great, your Honor. Thank you.

THE COURT: All right, you'll let me know if you want to -- take a ten minute break.

MR. BENNETT: Thank you.

(Continued on next page)

THE COURT: Ms. Holland?

MS. HOLLAND: Yes, your Honor. We don't believe that the switch that Dr. Owens talked about to universal calibration makes any difference to the infringement of those molar fraction claims and what we'd like, your Honor, is a representation on the record from Mylan that they actually think they have a good faith basis to believe there is a reason to contest infringement of the molar fraction claims based on this data or else this whole thing is just a really futile exercise.

THE COURT: Is that what you're doing, Ms. Bloodworth?

MS. BLOODWORTH: Your Honor, all we were pointing out is that Dr. Grant testified that he used data relied upon by Mylan for the purpose that he relied upon it for. First of all, that premise is factually incorrect. Dr. Grant had no representations from Mylan at the time he put that data to that use. Second point is that that data, even in Mylan's opinion that he says wasn't used for Mylan for that purpose, Mylan never believed that would be sufficient to do with it what Dr. Grant proposed to do. It's a failure of proof on plaintiff's part that they have checked that box that they have shown that there was an accurate, suitable method for those molar fractions. That's specifically why I wrote to Ms. Holland at the end of August and asked whether she was going to be resting on the infringement reports that she put in December in light

of our major amendment. If those representations had never been made to Dr. Grant, that was the basis of his opinion for using that data.

MS. HOLLAND: The concern here, your Honor, is Mylan never put in an expert report on that issue. What Ms. Bloodworth is talking about now, checking the box, I think what she was saying is she's just going to put us through our proofs even though Mylan didn't have any reason to believe they didn't infringe those claims. I believe what she's talking about now is to have yet another round at looking at this empower data.

THE COURT: What data?

MS. HOLLAND: The underlying data, the empower data, which is what Dr. Grant looked at for his original molar fraction claims. I still haven't heard any representation from counsel that they really have any recent to contest they infringed those claims. Seems to me they just want to find a reason to put us to our proofs.

MS. BLOODWORTH: Your Honor, what I'm getting at is the fact that Dr. Grant's methodology for claiming that Mylan did this slice method and calibrated this curve and determined that we had over 75 percent between 2 to 20, first of all didn't happen, it's factually incorrect. Second of all, we gave Teva the empower data for the UC amendment that they requested in June.

MS. HOLLAND: No.

MS. BLOODWORTH: They requested the underlying information. I can produce the cover letters, I can produce the thousands of pages of data that we provided to them and when we were on the phone with your Honor about Sandoz' supplemental discovery and I can provide the e-mail to your Honor as well when I asked in light of Mylan's major amendment is Teva planning on putting on additional information than what they provided in their expert reports and the answer was no, we don't intend to. So that's the basic flaw in Dr. Grant's analysis. Mylan has never used this --

THE COURT: You're going to argue from this testimony that Dr. Grant's analysis was flawed and that therefore Teva has not proven infringement.

MS. BLOODWORTH: Not necessarily a scientific analysis, but his belief that Mylan calibrated, that Mylan generated a calibration curve for the purpose that he put it to, which is what I asked him on his cross-examination --

THE COURT: I'm just trying to figure out what the goal of all of this is, that if you're going to argue that they failed in their burden in proving infringement because of this impeachment of Dr. Grant?

MS. BLOODWORTH: Yes, your Honor.

MS. HOLLAND: Your Honor, I think that confirms what I said, which is that there is no good-faith basis on Mylan's part to think they don't meet the limitations. This wasn't an

expert report saying we don't meet those molar fraction limitations. We think this is just an exercise of futility at this point.

MS. BLOODWORTH: Teva has not submitted an expert report so that Mylan can rebut it. I gave Teva every opportunity. Here this morning is the first time I ever heard from Teva on this issue. We produced Dr. Owens' documents he was going to be relying upon. I went affirmatively to Ms. Holland and asked her --

THE COURT: I'm not going to get involved now with this. I don't doubt what either of you told me. Ms. Holland, what do you want to do?

MS. HOLLAND: So, your Honor, at this point, I mean, as we said, we don't really believe there's any difference in the data, but what we could do is if Mylan produces this empower data which we don't have yet, this is electronic data, underlying electronic data, data that has not been produced to us, if we can get that from Mylan by tomorrow, we're not positive, but we're hopeful that Dr. Grant can address this issue in his rebuttal case. He's coming back with rebuttal.

THE COURT: I think you believe you have turned it over, Ms. Bloodworth.

MS. BLOODWORTH: Your Honor, we provided it in the format that was required by the parties in their e-discovery stipulations. Now she's asking for the underlying raw data

from the machine. So that's different. We provided the data in June. I have not heard any objection about the format of the data that was provided. We have had -- I don't believe that Teva has any right at this point in time to go in and do new infringement discovery when they have had every opportunity and every piece of paper that they needed to do that back in April when we were still in infringement discovery, your Honor, I might add.

Teva came to us, they asked us to do supplemental infringement discovery under the supplemental Sandoz claim construction. We said okay. We said you should have done it during the expert phase, it was well known to you, but okay, do that extra discovery. They asked for extra data. We gave them extra data. Then we had --

THE COURT: Turn it over, Ms. Bloodworth.

MS. BLOODWORTH: Your Honor, it's actually I think in a machine in India, so I don't think I can physically do it by tomorrow.

THE COURT: Okay.

MS. BLOODWORTH: And, your Honor, are we going to be allowed to evaluate or have any discovery on what Teva is now planning on doing or --

THE COURT: Fair enough. I'll see what Teva is going to do.

MS. BLOODWORTH: Okay, your Honor, so I will work with

Ms. Holland and let you know when I can provide them with that data.

THE COURT: Did you want to do any cross of Dr. Owens today?

MS. HOLLAND: I think we will proceed with the cross, your Honor.

THE COURT: Okay.

MS. BLOODWORTH: Your Honor, may I please provide copies to the Court for the foundation of what we've been discussing here today?

THE COURT: Yes. Look, I'm not finding fault because, frankly, I don't know what's been going on. As I said, I don't doubt either of your sets of representations, but I'm not going to get involved in the minute discovery process here about who said what to whom and what possibly the right result should be if I were to find some fault. Let's figure out what the truth is here, and, not about your interactions, but about what's going on with this product and this ANDA so you're going to turn over whatever data you may need and we'll have another discussion about whether you're entitled to do something more with their rebuttal. But this does have to come in and again, I'm not finding fault with anybody today. It's not good seeing this going on; first Sandoz and now Mylan.

MS. BLOODWORTH: Your Honor, I regret it, but I did --

THE COURT: All right. Well, we're going to catch up

and fix it. I gather you don't anticipate having Dr. Owens back after his cross.

MS. HOLLAND: We don't anticipate that, your Honor.

THE COURT: All right, then we can finish with Dr. Owens. Go ahead, Mr. Bennett.

CROSS-EXAMINATION

BY MR. BENNETT:

Q. Good morning, Dr. Owens.

A. Good morning.

Q. Dr. Owens, we can agree that you are not an expert with respect to molecular weight characterization, right?

A. I would agree I'm not an expert on exclusion chromatography.

Q. In fact, you've never even performed size exclusion chromatography yourself, right?

A. I have not done that myself, that is correct.

Q. And before your work with this product, you had no experience working with complex polypeptides, right?

A. That would also be correct.

Q. So you have no expertise as to the determination of the molecular weight of copolymer-1, right?

A. I would not be an expert in peptide chemistry. As far as the molecular weight determination is concerned, I understand the output of the experiments that have been performed.

Q. But in terms of having sufficient experience to call

yourself an expert in determining molecular weight of copolymer-1, you just don't have it, right?
A. I would not consider myself an expert in copolymer-1.
Q. Now, I'd like to turn to the amendment that you were discussing with Ms. Bloodworth, and if you pull that binder that I have for you, it's the document that's been marked DTX 1411. I have a tab marked for you in your binder. If you could turn to page ending in Bates number 150489. Are you with me, sir?
A. I see that.
Q. Now, the bottom of this page, the table of molecular weight data, right?
A. The bottom of this page does include a series of molecular weight data, yes.
Q. And if we look at the left hand column of this table, there's a reference to some lots of glatiramer acetate products, right?
A. There are.
Q. And the first three lots that are mentioned there are the pivotal batches of Mylan's glatiramer acetate active ingredient, right?
A. Those are the active ingredient lots, yes.
Q. And if we look a few rows below there's three rows there that begin with the letters WV, do you see that, sir?
A. I do.

Q. And those are the pivotal batches of Mylan's finished drug product, right?
A. Those are batches of a finished drug product, correct.
Q. And all of the molecular weight data that is represented on this table, sir, was calculated using the peptide standards that you discussed earlier today, right?
A. This particular set of molecular weight data, the Mn and Mw and Mp would come from the original ANDA data that was presented so that would be the against the peptide standards.
Q. And you put it in the April amendment that you just filed with the FDA, right?
A. It was placed back into the April amendment as a demonstration to calculate poly dispersity.
Q. And you didn't tell the FDA in that April submission that this data was somehow inaccurate, right?
A. Actually, I believe if you were to look further in this document in the next page, we discuss universal calibration and that it's reliable and we provide a similar set of data.
Q. Right, and you've said that that meant it was reliable, but you didn't say this data was inaccurate, right?
A. What we said about universal calibration is that it's more reliable and that's why we're changing.
Q. But you didn't tell the FDA, sir, that this data was inaccurate, right?
THE COURT: He's answered that. They did not,

correct?
A. No. What we told the FDA --
THE COURT: In those words you did not say it was inaccurate. I think that's all we're getting at here.
THE WITNESS: Correct, your Honor. What we told the FDA is that the universal calibration that's presented on the subsequent page relies more confidence in the Mn and Mw values.
Q. So if we move to the next page of this document, sir, and the very first paragraph you make reference to the universal calibration method, right?
A. That is correct.
Q. And when you mentioned universal calibration you dropped a footnote there, do you see that?
A. I do see that.
Q. And that footnote is to an article from 1967, right?
A. That is correct. That's the reference.
Q. So Mylan's representing to the FDA here that this universal calibration method they're using is something that was described in literature from 1967, correct?
A. The literature reference is intended to only reference the universal calibration as a technique and not necessarily the method that is actually being performed by Mylan.
Q. The technique that you're describing here of universal calibration is what Mylan is using to characterize its product, right?

A. It is a universal calibration, but it is a method that had to be developed for the glatiramer acetate product.
Q. Now, if you turn to the next page, sir, and we look at the top of this page, the table, do you see that?
A. I do.
Q. And these are molecular weight data that Mylan generated using universal calibration, correct?
A. These would be data from universal calibration.
Q. Again, we see reference on the left-hand side to the pivotal batches of Mylan's product, right?
A. We see the reference to the active pharmaceutical ingredient in finished product lots, correct.
Q. And those are the same batches of active ingredient that were analyzed using the peptide standard we saw earlier in the document, correct?
A. Those would be the same.
Q. They were made the same way, right?
A. They are the same products.
Q. And it's also true with respect to the WV lots in this table, right?
A. Again, those would be the finished products represented in the ANDA, yes.
Q. And the peak molecular weight values for all of these batches fall between 5 to 9 kilodaltons, right?
A. Yes.

Q. All right, we're going to pull that down. Now, Dr. Owens, the Mylan ANDA that you were involved in was seeking to market a generic form of Copaxone, right?
A. We are seeking to gain approval for a generic form of Copaxone, correct.
Q. And the active ingredient in Copaxone is glatiramer acetate, correct?
A. That is correct.
Q. And the active ingredient in Mylan's proposed product is also glatiramer acetate, right?
A. It would be required to be identical and therefore glatiramer acetate.
Q. And glatiramer acetate is composed of four amino acids, are you familiar with that, sir?
A. I am.
Q. And the glatiramer acetate has those four amino acids in a certain relative proportion, right?
A. Yes.
Q. And Mylan typically expresses the relative proportion of those four amino acids as a mole fraction, right?
A. I believe that is the specification, correct.
Q. Now, if you could, Dr. Owens, I'd like you turn to tab PTX 320 in your binder? If you could highlight that information in the top right, Mr. Chase. Do you recognize this as module 3 from Mylan's ANDA, sir?

A. That would be consistent with listing for module 3 from the ANDA.

MR. BENNETT: Plaintiffs move for admission of PTX 320, your Honor.

THE COURT: Any objection?

MS. BLOODWORTH: Not at this time, I would just ask Mr. Bennett if he would let me know the page number so it could be published privately prior to showing it.

THE COURT: Admitted with that understanding.

(Plaintiff's Exhibit PTX 320 received in evidence)

Q. If you'd move to the page ending with the Bates number Mylan 236, sir?

A. Can you repeat the number, again?

Q. Yes, it's the Bates number Mylan 236.

A. Thank you.

Q. Could you first focus on the top of the page, Mr. Chase? This is a portion of Mylan's ANDA that's discussing the drug substance of this product.

A. That's correct, that's what the top of this page indicates.

Q. And if we could move down, Mr. Chase. Mylan's discussing the nomenclature for its products in this portion of the ANDA, right, Mr. Owens?

A. This particular page indicates nomenclature, yes.

Q. And this portion of the ANDA is describing, again, Mylan's product as glatiramer acetate, right?

A. That is what's listed as the recommended international non-proprietary name.
Q. And there's also a list of synonyms provided in this document, right?
A. It does list synonyms.
Q. And one of the synonyms for glatiramer acetate that Mylan is representing to the FDA is copolymer-1, right?
A. I do see that listed on the document.
Q. All right. Dr. Owens, you talked a little bit on your direct about some process work that Mylan was involved in, is that right?
A. When we discussed synthetic processes.
Q. Correct. And there was some characterization work that Mylan performed with respect to a bromotyrosine purity, correct?
A. That is correct.
Q. And there was a change made to the manufacturing process to address this bromotyrosine impurity, correct?
A. There was a change that was made to remove bromotyrosine from the copolymer.
Q. And Mylan has consistently referred to the bromotyrosine as an impurity, right?
A. It's an impurity, but it's actually integrated into the polymer itself.
Q. But it's an impurity, right?

A. Again, the bromotyrosine would be incorporated into the polymer and that would be an impurity within the polymer system.
Q. And Mylan has represented to the FDA that this bromotyrosine is an impurity, right?
A. We have characterized it as an impurity in our amendment.
Q. And this is one of a number of impurities that Mylan controls in the product, right?
A. I don't recall the impurities that are controlled in the product.
Q. Dr. Owens, if you could turn to the page ending in Bates Mylan 683? Do you recognize this as the portion of the modular discussing the impurities in the proposed Mylan product?
A. This is the portion of the modular that would be relevant to impurities.
Q. If you turn to page Mylan 685? Mylan 685, sir, are you there?
A. I'm on that page.
Q. And this page lists seven different impurities of Mylan as controlling in its glatiramer acetate product, right?
A. On this particular page lists impurities that are associated with solvent impurities of the copolymer.
Q. And if we turn to the next page, Mylan 686, there's two more impurities that are listed here, right?
A. There are two additional impurities listed.

Q. One of which is the bromotyrosine impurity that we've discussed earlier, right?
A. Bromotyrosine is listed here, yes.
Q. So bromotyrosine is one of a number of impurities that Mylan is seeking to control in the product, correct?
A. Bromotyrosine again is listed as one of the impurities.
Q. And that's standard practice in the pharmaceutical industry, right, you control impurities in your pharmaceutical product, right?
A. You would control impurities in your pharmaceutical product or if the levels were too high you could remove them or make every attempt to remove them.
Q. Mylan has not performed any testing that would show that this bromotyrosine impurity has any impact upon the safety or efficacy of its proposed product, right?
A. I believe that would be unknown.
Q. And in fact, the reason that Mylan was concerned about this impurity was to just make sure that its product was the same as Copaxone, correct?
A. The reason that we were concerned about the presence of bromotyrosine is that it is incorporated in the copolymer and it did represent a difference from what we were observing in Copaxone. We viewed that as a regulatory risk and it is present at substantial levels in the original Natco material.
Q. Now, you never -- the process change that you implemented,

which was the use of phenol was meant to reduce this impurity, right, this bromotyrosine impurity?
A. The intent was to reduce the amount of bromotyrosine present in the polymer.
Q. And that change was not implemented to adjust the mole fraction of your product, right?
A. The intent was to remove bromotyrosine from the copolymer.
Q. Right, so that had nothing to do with the mole fraction of your product, right?
A. I'm not aware of the impact it would have on the mole fraction of the product.
Q. And the mole fraction of the product had no input into the decision to use phenol, right?
A. Our focus was on removing bromotyrosine.
Q. Now, the bromotyrosine issue was what you would characterize as a scaleup issue, right, Dr. Owens?
A. I would not characterize it as a scaleup issue.
Q. Okay. If you could turn in the same document to Mylan 614. This is the section of the ANDA that discusses the manufacturing process development, right, Dr. Owens?
A. That is correct.
Q. And if we turn forward to Mylan 641. Hold on, Mr. Chase.
THE COURT: I'm sorry, what document are you on?
MR. BENNETT: PTX 320, your Honor.
THE COURT: You're still on that?

MR. BENNETT: Yes.

THE COURT: All right.

Q. If you look at the first paragraph of that page, sir, here Mylan and Natco are representing to the FDA that the problem with high bromotyrosine impurity was something that was encountered during the scaleup of the process to make glatiramer acetate, right?

A. That's what this particular document states in this text.

Q. And you have no reason to disagree with that, right, sir?

A. I have no reason to disagree with that, although I don't know what the process was that was being scaled up.

Q. Okay. So this bromotyrosine impurity issue was something that was encountered during scaleup of the manufacturing process, right?

A. We observed bromotyrosine with the first materials that were received from Natco.

Q. And by that time Natco had begun to scale the process, right?

A. Natco had represented those materials as a currently validated process which we subsequently asked for the process to be altered.

Q. So this portion of the document is referring to the implementation of a process described as above, right, so referring to some process described earlier in the document, is that correct?

A. It does have the sentence of glatiramer acetate process described as above.
Q. And if we could turn to Mylan 616, Dr. Owens. And the first paragraph, which is an overview of the process.
A. I see that.
Q. And here Mylan and Natco are describing glatiramer acetate as a copolymer that's been described in the 1971 publication by the Weizmann Institute, right?
A. This particular document does have a reference to the European Journal of Immunology, and the Weizmann Institute.
Q. And if we look second to last sentence, Mylan and Natco are representing to the FDA that glatiramer acetate has amino acid ratios of 6:2:5:1, right?
A. I see the sentence. But I cannot tell if it's in reference to the publication or not.
Q. Now, if we move along within this manufacturing process development report, sir, and specifically I'm looking at page Mylan 622.
MR. BENNETT: This just appears on the private screens, your Honor.
THE COURT: Okay.
Q. And this is a representation of the process that Natco was using to make glatiramer acetate before the implementation of the use of phenol, right?
A. This would be a schematic that has the process listed

without phenol, correct.
Q. Okay. And again, if we -- sorry, one last question on that schematic, sir. At the very bottom of that schematic, the end product for that product is listed as glatiramer acetate, right?
A. That's what's listed on the page.
Q. And if you could turn forward to page Mylan 637, sir? And again, this is a description of the debenzylation step of the manufacturing process that does not contain any description of the use of phenol, right?
MS. BLOODWORTH: Objection, your Honor. Misrepresents the document.
THE COURT: I'm sorry. Why don't you reask the question again. What's your question?
Q. The question, your Honor, is, Dr. Owens, this description of the debenzylation reaction contains no mention of phenol, right?
A. Just give me a minute, if I could, just to read the paragraph?
(Pause)
A. This particular paragraph does not have phenol mentioned within it.
Q. If we move to the next page there's a table of experimental data from batches made according to this process, correct?
A. I can't necessarily tell if these were experiments from

that particular process. It is the following page.
Q. The batch numbers for these batches would indicate to you that these were made in 2007, right?
A. That's my understanding of the batch numbering system.
Q. I think you testified on your direct, sir, that the bromotyrosine issue that was resolved with the addition of phenol was not until 2008, correct?
A. It was under discussion in 2008.
Q. It was not implemented until thereafter, right?
A. That's my understanding.
Q. If we look at the tyrosine amounts for these batches, they are.'098, .091 and .094, right?
A. I do see those values on the table.
Q. And these were batches made without using phenol, right?
A. Again, I can't tie this directly to the previous page, but they're batches from 2007.
Q. So it's reasonable to conclude that they would have been made without using phenol, correct?
A. I cannot say that with absolute certainty.
Q. Now, if we could turn to the portion of the document that discusses the use of phenol, which is Mylan, specifically Mylan 642. And we see here a table of data for some samples that were made using a debenzylation reaction with the addition of phenol, right?
A. The table indicates glatiramer acetate prepared using

phenol as a free growing scavenge and that's what's written on the document.

Q. If we look at the tyrosine values for those samples it's .089, .086 and .085, correct?

A. I see those values represented on this page.

Q. Those values are lower than the values we just looked at on the previous table, right?

A. Those values would be lower.

MR. BENNETT: One last line, your Honor.

Q. You mentioned earlier, Dr. Owens, that in addition to some molecular weight characterization Mylan also performed some biological characterization of your proposed product, correct?

A. That is correct.

Q. And one of the biological characterization assays that you have used is the EAE model, right?

A. There is an EAE model, actually two EAE models represented in the characterization document of the ANDA.

Q. And those tests have established that both Mylan's products and Copaxone are both effective on the EAE model, right?

A. Those tests show the Copaxone and Mylan's glatiramer acetate performed in an equivalent fashion in the EAE model.

Q. And they're both reflected in that model, right?

A. I would not relate it to effectiveness or efficacy of the drug. I would relate it only to comparability of the two drugs.

Q. All right, if you turn to tab PTX 318, sir? And this is a document that you used on direct, correct?
A. That's correct.
Q. This is the biowaiver portions of Mylan's ANDA, correct?
A. This is would be the waiver portion of in vivo studies, correct.
Q. I'd like you to turn to page Mylan 124. And here you see a discussion of Mylan's biological characterization using the EAE model, correct?
A. I do see that.
Q. And just to review, EAE is an animal model for multiple sclerosis, is that right?
A. It is an animal model.
Q. If you look at the first sentence of the second paragraph you see there that it states GMA, which is Mylan's proposed product, and Copaxone were evaluated in an EAE assay to assess the relative biological effect of the products on disease progression, right?
MS. BLOODWORTH: Objection, your Honor. We're well beyond Dr. Owens' scope of his original direct examination.
THE COURT: I'll permit it.
A. I do see the sentence, yes.
Q. If we move forward in the document to Mylan 130. This is still a discussion of the biological characterization that Mylan was performing with the EAE model, correct?

A. This would still be a discussion of EAE.
Q. And if you look at the second paragraph on this page, sir, and the first sentence states that both GMA, which is Mylan's products, and Copaxone treatments were demonstrated to have significant effects on the onset and the early phase of disease state progression, right?
A. I see that sentence. It basically states that both compounds performed equivalently in this model.
Q. And they both demonstrated significant effects on the onset and early phase of disease state progression, right?
A. In this particular model, that's what it's referencing.
Q. And it goes on to state that both GMA and Mylan's products with Copaxone treatments were demonstrated to have equivalent reductions in EAE severity during the early phase of the disease, right?
A. That's what it states and that's the comparability that's made with using the EAE between the two products.
Q. According to Mylan's testing its products and Copaxone produced similar results on the EAE model, right?
A. The goal of this experimentation was to demonstrate that Mylan's product and the Copaxone yield equivalent results in this particular animal model.
MR. BENNETT: Your Honor, with that, plaintiffs move PTX 318 into evidence.
THE COURT: Any objection?

MS. BLOODWORTH: Just the confidentiality concern.

THE COURT: Absolutely. Thank you, Ms. Bloodworth. Admitted.

(Plaintiff's Exhibit PTX 318 received in evidence)

MR. BENNETT: Plaintiffs have no further questions, your Honor.

THE COURT: Okay. Any redirect?

MS. BLOODWORTH: No, your Honor. Thank you.

MR. ACKER: Your Honor, Sandoz has a couple of questions, if I might.

THE COURT: We haven't done this before, but --

MR. ACKER: Four or five questions.

THE COURT: All right, go ahead.

MR. ACKER: Thank you.

THE COURT: Perhaps we should talk about -- this is unusual, to say the least.

MS. HOLLAND: We would have an objection to it, your Honor. We don't see how Sandoz should be questioning Mylan, a co-defendant in this case. They haven't put Dr. Owens on the witness list to question him.

THE COURT: Let me ask you this. Are you cross examining to bring out -- well, what are you doing?

MR. ACKER: I'm going to ask four questions to clarify Dr. Owens' testimony on one specific issue.

MS. BLOODWORTH: Your Honor, may we take a break?

THE COURT: Maybe you should discuss this with Ms. Bloodworth.

MS. BLOODWORTH: And before we take a break may I move into evidence DTX 1411?

THE COURT: Yes. Admitted.

(Defendant's Exhibit DTX 1411 received in evidence)

THE COURT: Let me know when you've got it all sorted out.

(Recess)

(In open court after the recess)

THE DEPUTY CLERK: All rise.

THE COURT: Please be seated.

Mr. Bennett.

MR. BENNETT: Your Honor, the defense have conferred. I guess if we get some sense of what the scope of this examination would be --

THE COURT: I guess we'll know in four or five questions, right.

MS. BLOODWORTH: Your Honor, I was thought it was two.

THE COURT: Ms. Bloodworth, you're not concerned?

MS. BLOODWORTH: It's my understanding that it's limited to Dr. Owens' cross-examination questions point of clarification, so I'm not concerned, no.

THE COURT: Okay. Go ahead.

CROSS EXAMINATION

BY MR. ACKER:

Q. Good morning, Dr. Owens.

A. Good morning.

Q. In response to questions from Mr. Bennett, you testified that the universal calibration process that Mylan and Natco switched to in 2011 had to be developed. Was that testimony accurate?

A. It was something that we absolutely wanted to have developed and placed into the ANDA.

Q. And that development was not done by Mylan or Natco, but rather you had to hire a consultant to do that, to develop the universal calibration, correct?
A. There was a third party involved with the development of the universal calibration, that is correct.
Q. And as I understand your testimony, that process with the third party to develop that universal calibration method took over a year, is that right?
A. The development program began in late 2009, with the culmination of the submission in April of 2011.
MR. ACKER: That's all I have. Thank you, your Honor.
THE COURT: Okay, Mr. Bennett, anything further?
MR. BENNETT: Nothing further, your Honor.
THE COURT: Anything else from anybody?
MS. BLOODWORTH: Thank you, Dr. Owens.
Thank you, your Honor.
THE COURT: All right. Thank you, Dr. Owens, you're excused. You may step down.
(Witness excused)
THE COURT: Next witness.
MR. ANSTAETT: Your Honor, Mylan calls Dr. Stephen Kent.
MS. BLOODWORTH: Your Honor, if I may approach? I promised the Court Reporter a binder.
THE COURT: Sure. Thank you.

STEPHEN B. H. KENT,

called as a witness by the defendant,

having been duly sworn, testified as follows:

DIRECT EXAMINATION

BY MR. ANSTAETT:

MR. ANSTAETT: And, your Honor, I want to make sure I think we're still in the process of handing out the binders.

THE COURT: When we get settled.

MR. ANSTAETT: Sure.

THE COURT: Dr. Kent, you can use the binders of course, but looking at the documents on that screen and that little screen, so if you're like me, it may be easier than to try to move these things around.

THE WITNESS: Thank you very much.

MR. ANSTAETT: Your Honor, if I may approach and give Dr. Kent a laser pointer?

THE COURT: Sure.

MR. ANSTAETT: I think we're all ready.

THE COURT: I think you can proceed. Go ahead.

MR. ANSTAETT: All right. Thank you, your Honor.

Q. Good afternoon, Dr. Kent.

A. Good morning.

Q. Good morning. Could you describe your educational background for the Court, please?

A. Yes, I have three university degrees, a bachelors degree in

chemistry and biochemistry, a double major, a Master's Degree in a combined chemistry biochemistry program with a thesis on the sequencing of peptides by mass spectrometry, and a Ph.D. in chemistry at University of California Berkeley with a thesis on nuclear magnetic resonance studies of chemically modified proteins.

Q. Dr. Kent, did you do any post doctoral work?

A. Yes. From 1974 through 1981, I worked with Bruce Merrifield at the Rockefeller University here in New York, first as a post doctoral fellow, then as assistant professor.

Q. Who is Bruce Merrifield, please?

A. Bruce Merrifield was the inventor of solid phase peptide synthesis, the most commonly used way of making peptides by chemistry, for which he received a Nobel Prize in chemistry in 1984.

Q. All right. Doctor, could you describe, generally, for me the type of work you've done since completing your post doctoral work?

A. Yes. Throughout my research career, then and subsequently, my work has been focused on the chemical synthesis of peptides and proteins.

Q. All right. And what positions have you held?

A. I've held positions both in academia and in industry. The principal positions that I've held in academia were on the senior research faculty at the California Institute of

Technology. I was professor and member of the Scripps Research Institute, and I'm currently at the University of Chicago.

In and industry the principal position that I held was as president and chief scientific officer of Griffin Sciences.

Q. And what was Griffin Sciences?

A. Griffin Sciences was a start-up biotechnology company focused on developing chemically synthesized proteins as human therapeutics.

Q. All right. Now, you said you are at the University of Chicago. How long have you been there?

A. I've been there exactly three days less than ten years.

Q. All right. And what is your position at the University of Chicago?

A. I'm professor of chemistry and professor of biochemistry and molecular biology.

Q. All right. And in that position, what are your responsibilities?

A. Primary responsibilities are teaching and the training of graduate students, and in addition I lead and direct the activities of my own research group which typically consist of about ten persons.

Q. All right. And what courses do you teach, please?

A. I teach graduate courses in the synthesis of peptides and proteins, and the coming year I'll be teaching a graduate course in chemical biology.

Q. Have you published any articles in scientific journals?
A. I published approximately 225 articles in scientific journals, about 185 of those were peer-reviewed articles.
Q. All right. And are you a peer reviewer for any journals?
A. Yes. I'm a peer reviewer for a number of journals, including the top scientific journal such as Nature and Science, and also the top chemistry journal such as Journal of the American Chemical Society and the Journal of the German Chemical Society.
Q. All right. And have you presented any scientific lectures?
A. I'm sorry, could you repeat the question?
Q. Sure. Have you presented any scientific lectures?
A. Yes. For example, the last ten years since I joined the faculty at the University of Chicago, I presented approximately 125 scientific lectures at international meetings and leading academic institutions. And, for example, at this time last year I was keynote speaker at the Roche Peptide Symposium in Colorado, and I gave around the same time last year, award addresses to the European Peptide Symposium on the Japanese Peptides Symposium.
Q. All right. Dr. Kent, are you the named inventor on any United States patents?
A. I'm the named inventor on 42 United States patents.
Q. Have you received any awards related to your work with peptides and proteins?

A. Yeah. I've received seven international awards for my research activities. The top four awards in peptide science were wide, so those are from the -- well, it's the Rudinger Medal from the European Peptide Society, the Akabori Medal from the Japanese Peptide Society, and the du Vigneaud and Merrifield awards from the American Peptide Society.

In addition, I received the Hirschmann award in peptide chemistry from the American Chemical Society, if I didn't already mention that. And earlier this year I received the Aider award in bioorganic chemistry. That's only six, but we'll probably stop there.

Q. We'll call that close enough.

Doctor, could you describe, generally, your experience in analyzing the amino acid content of peptides and proteins?

A. Yes. Actually as an undergraduate, I did summer research on where I brought into action an amino acid analyzer, and then performed amino acid analyses on proteins from various sources. And for the 20 years or so after that, amino acid analysis was the primary method for characterizing the peptides that I was making by chemical synthesis, and also for characterizing the proteins that I was working with.

Q. How many amino acid analyses have you performed or overseen during your career?

A. It would have been many hundreds of amino acid analyses.

Q. All right. And Nick, could we please take a look at

DTX-1963.

Dr. Kent, is this an accurate copy of your curriculum vitae?

A. As of March 2011, yes.

Q. All right.

MR. ANSTAETT: And, your Honor, I would move admission of DTX-1963.

THE COURT: Admitted.

(Defendant's Exhibit 1963 received in evidence)

MR. ANSTAETT: Your Honor, Mylan offers Dr. Kent as an expert in the chemical synthesis and analysis of peptides and proteins?

THE COURT: Any objection.

MS. HOLLAND: No objection.

THE COURT: All right. Then, Doctor, you're accepted by the Court as an expert.

Go ahead.

THE WITNESS: Thank you.

Q. Doctor, you submitted three expert reports in this case?

A. That's correct.

Q. Did one of those reports consider whether Mylan's proposed glatiramer acetate product infringes the patents in suit?

A. It did.

Q. All right. And what was your conclusion?

A. My conclusion was the Mylan glatiramer acetate proposed

product does not infringe the patents in suit.
Q. All right. Nick, could we take a look at the first slide, please.
Is this the definition of a person of ordinary skill in the art that you applied in reaching your opinions in this case?
A. It is.
Q. And doctor, I'm going to just ask you if you would, please, read the definition for the record?
A. "In 1994, a person of ordinary skill in the art of the patents in suit would have an advanced degree or equivalent in a chemical or biological discipline and significant experience in one or more of the following areas: The synthesis, fractionation or characterization of peptide polymers such as their amino acid composition and/or hydro dynamic and structural properties as applied to proteins, synthetic peptides and/or poly disperse mixtures.
Q. All right. Doctor, have you reviewed the patents in suit?
A. I have.
Q. If we could see PTX-1, please. Is this one of the patents that you reviewed?
A. Yes, it is.
Q. Who are the inventors on this patent?
A. The inventors are listed as Eliezer Konfino, Ramat Gan, Michael Seta -- I'm sorry, that's a place -- Michael Seta,

Dvora Teitelbaum and Ruth Arnon.

Q. Who is you understanding is Mr. Konfino?

A. Mr. Konfino was a process research chemist at Teva, I believe, from 1957, until he retired in 1991 at the end of 1991.

Q. All right. And what did you do to gain an understanding of some of the work Mr. Konfino did while he was at Teva?

A. I looked at Mr. Konfino lab books, and I also looked at documents that he had authored while he was at Teva.

Q. All right. And did you review Mr. Konfino's deposition transcripts?

A. I did review his deposition transcripts, yes.

Q. All right. Now, Doctor, did you help prepare some demonstrative exhibits to explain the basis for your opinions in this case?

A. I have.

Q. And why don't we take a look at the first animation, please. And, Doctor, I'm going to ask you some questions about this.

What are we looking at here, Doctor?

A. This was the first page of the patent that we just remarked on. It's referred to usually as the '808 patent, and now we've leafed through into the patent to look at example four.

Q. And what do we see here?

A. What's highlighted in example four here is the first step

in preparing copolymer-1 as described in this patent. And that consists of a random copolymerization process involving four amino acids.

Q. All right. Proceed.

A. And we'll go on to demonstrate that in an animation, yes.

So this reaction is carried out in water solution as seen here. These are the four amino acid, activated amino acid building blocks that are used in the copolymerization process.

Q. All right. And what do we see on the -- well, first let me ask you this, if you could identify the four amino acids here, please?

A. Yes. From left to right alanine, glutamic acid, lysine and tyrosine.

Q. And what do we see on the glutamic acid and the lysine?

A. Yes. Glutamic acid and lysine both contain additional reactive functionalities in order to avoid those interfering with the formation of linear polypeptide chains in the polymerization reaction. These side chain functionalities are blocked were, we usually call protected, and we've symbolized here on the side the benzyl protecting group of glutamic acid, with the gray hemispherical object and the trifluoracetyl group of lysine as the rectangular metallic object.

Q. All right. Proceed, please.

Dr. Kent, what are we -- what do we see happening here?

A. On this initiator is added to start the polymerization reaction. And as you can see highlighted on the right, this leads to the formation of linear polypeptide chains throughout the reaction medium, throughout water solution, so many millions of random sequence polypeptide chains are being formed, until the supply of building blocks is exhausted or until the reaction is terminated.

Q. Then how many of the polypeptide chains have the same sequence?

A. The diversity that is possible in a reaction of this kind is so great that essentially none of the product polypeptide chains will have the same amino acid sequence.

Q. All right. And how many chains are being formed?

A. Many millions, very very large number.

Q. All right.

A. So at this point we formed protected co-polymer-1. And the next step is referred to, as we've just heard, is either the debenzylation step or the first deprotection step, in which protected co-polymer-1 is treated with 33 percent HBr hydrobromic acid and acetic acid.

Q. Would you --

A. This removes the benzyl protecting group just from the glutamic acid residues throughout the copolymer mixture.

Q. And what are we seeing here, Doctor?

A. Well, now we're representing the reaction that happens with

treatment with HBr and acetic acid. In A moment you'll see this side chain protecting group and all the other glutamic acid side chain protecting groups throughout the product mixture are removed by the strong acid conditions, to give trifluoracetyl co-polymer-1.

Q. All right. And what do we see here, Doctor?

A. This is the second deprotection step, the removal of the trifluoracetyl groups from the side chains of the lysine residues and the copolymer. This is done with a reagent called piperidine or piperidine.

Q. All right.

A. And so the trifluoracetyl co-polymer-1, we've highlighted a couple of the lysine residues, but this applies to all of them. The piperidine removes the side chain protecting groups to give the deprotected co-polymer-1 product mixture.

Q. All right. Now, is this the final copolymer-1 product at this stage?

A. It's the final copolymer-1 product as described or as formed by the process described in the '808 patent.

Q. All right. And if we can continue, Nick.

Now, if you wanted to determine the amino acid content of the copolymer-1 composition, how would you go about doing that?

A. Well, you would take a sample and you would first so you could, for example, this sample the peptide chain, and in order

to determine the amino acid composition, you would heat in aqueous acid to break it back up into its amino acid components. Those would then be separated, and the amount of each amino acid would be measured as symbolically represented here.

Q. All right. And what is that process called?

A. Hydrolysis and amino acid analysis.

Q. All right. Okay. And we can take that down.

Dr. Kent, is what you just described for the Court how the Teva patents teach making co-polymer-1?

A. Yes, it is.

Q. All right. Now, based on your review of Mr. Konfino's documents and other Teva documents in this case, is what you just described what actually happens if you follow the process for making co-polymer-1, described in the Teva patents?

A. No, it's not what actually happens.

Q. All right. Could you please explain?

A. Yes. The documents that I've reviewed make it clear that Mr. Konfino and others at Teva were aware that a side reaction occurred in the process that we've just described.

Q. All right. And what is that side reaction?

A. That was a side reaction that occurred in the HBr acetic acid first deprotection step, and it led to the formation of a 5th amino acid, bromotyrosine, present in the copolymer product.

Q. All right. And you referred to bromotyrosine as a fifth amino acid?
A. Yes. The English language is a little confusing on this point, but bromotyrosine is a chemically distinct amino acid different from the other four amino acids found in copolymer-1 as described in the '808 patent.
Q. All right. Nick, could we please see PTX-708T. And if we could, thank you, go to that page.
Dr. Kent, is this a document that you reviewed in coming to your opinions in this case?
A. Yes, it is.
Q. All right. And who is the author of this document, please?
A. The author is Mr. Konfino, one of the named inventors on the '808 patent.
Q. All right. And what is the date, please?
A. The date is August, 1991 for this report that Mr. Konfino prepared.
MR. ANSTAETT: Your Honor, I move admission of PTX-708T.
MS. HOLLAND: No objection.
THE COURT: Admitted.
(Plaintiff's Exhibit 708 received in evidence)
Q. Dr. Kent, did Mr. Konfino address the issue of bromotyrosine in this report?
A. He did.

Q. All right. And, Nick, could we see the page with Bates number TEV324554, please? If we could look at section two.

Dr. Kent, what is your understanding of what's being reported in section two here?

A. Well, this is a section which this report by Mr. Konfino describes the problem and its solution, and I'll read the first paragraph.

"Still in an early stage of work, one of the impurities of cop-1" -- that's co-polymer-1 -- "was identified as bromotyrosine. It was then proven that the presence of small amounts of free bromine in the HBr acetic acid are to be blamed for the formation of the said impurity."

Q. All right. Doctor, is that HBr acetic acid solution a reagent used in the first deprotection step that you just illustrated?

A. Yes. HBr acetic acid is the reagent used in the first deprotection step.

Q. All right. Doctor, did you help prepare a demonstrative exhibit to illustrate the problem described in Mr. Konfino's August 1991 memo?

A. I did.

Q. All right. Nick, if we could look at the second animation, please. And what are we -- what are we looking at here, Dr. Kent?

A. This is the cover page from Mr. Konfino's August 1991

report. And we're leafing into the section that I just read from in which Mr. Konfino describes, as shown on the highlighted section, that bromotyrosine is formed in the co-polymer-1.

Q. All right. And what are we looking at here, Dr. Kent?

A. We're back looking at animation of the copolymerization reaction with our four activated amino acid building blocks this is carried out in water. When an initiator is added, as you can see highlighted on the right, we're starting to form a random mixture of linear polymer chains, protected polymer chains, and --

Q. Now, at this stage is this the same protected copolymer-1 that we saw in the previous animation?

A. It is. This could, this protected co-polymer-1 product mixture is the same as we saw in the first animation.

Q. All right. We can continue then.

A. So now we're going to move into the step where he treat with HBr and acetic acid. And what I've tried to represent here in the animation is the fact that bromine is an impurity in the HBr acetic acid. Bromine molecules themselves consist of two bromine atoms joined to each other. But under the strongly acid conditions used in the first deprotection step, some of those bromine molecules break up to form reactive bromine ions, shown here as the red balls with the BRplus on them.

Q. And you use the word reactive. What did you mean by that?
A. Well, you refer to a chemical as reactive in terms of its potential to seek out and find partners for it to react with and join to. And bromine itself is somewhat reactive. One of the things that it does is form these BRplus ions, but the BRplus ions themselves are much more reactive. They're very very actively seeking out something to quench their thirst for reaction.
Q. All right. Nick, we can continue, please.
A. So now we go back to the HBr acetic acid step. And as before under the strong acid conditions, these side chain protecting group of the glutamic acid, the benzyl was removed from the glutamic acids throughout the protected copolymer.

However, in this case, because of the presence of the bromine impurity and the consequent reactive bromine ions, as shown here by the BRplus, something else happens. So if we can could go -- thank you. These BRpluses react with the side chains of the tyrosine residues throughout the copolymer mixture and form a 5th amino acid component present in the copolymer.
Q. And does this side reaction happen to tyrosines in just one of the polypeptide chains or throughout the mixture?
A. No. It happens randomly throughout the mixture to the extent of about 30 percent of the tyrosines being converted to the bromotyrosine.

Q. All right. And we can continue.
A. So now we go to the second deprotection step, the treatment with piperidine. And this removes the trifluoracetyl groups from the lysine side chains throughout the polymer giving us the deprotected copolymer-1 that is actually made using the process described in the '808 patent.
Q. And, Doctor, I'm going to ask you just to describe the two panels that we see here, please?
A. Well, on the bottom panel we see the representation of the copolymer-1 mixture as described in the '808 patent, and in the upper panel we see the co-polymer-1 mixture that is actually produced using the process described in the '808 patent, with the polymer chains product polymer chains containing bromotyrosine.
Q. All right. We can continue.
A. And that just highlights the presence of the bromotyrosine in the co-polymer-1 actually made in the process from the '808 patent.

So we go ahead and carry out the hydrolysis and analysis as before, we get the four amino acids and their relative amounts, as shown here.
Q. Okay. And if we could stop it here, please. What's the pulsating material up there over the tyrosine test tube?
A. What you're only analyzing for alanine, glutamic acid, lysine and tyrosine because bromotyrosine is a distinct

chemical compound, a distinct amino acid. It's not counted in any of the four amino acids that you're looking for. So this amount of bromotyrosine that's present in the polymer product remains uncounted in the amino acid analysis.

Q. All right. And what are the numbers at the bottom of the test tubes?

A. Those are the molar ratios that result from the actual process as described in the '808 patent.

Q. All right. And what does this molar ratio tell you about this co-polymer-1 composition?

A. It tells me that in the complex polymer mixture that, on average, there are six alanines for every one tyrosine. So these are ratios, molar ratios. So by definition we're talking about the amount of one amino acid compared to another amino acid. So about six alanines on average to one tyrosine, approximately two glutamic acids for every one tyrosine, and approximately five lysines for every one tyrosine.

Q. All right. And, Doctor, has the uncounted bromotyrosine affected this molar ratio?

A. Yes, I have.

Q. All right. Could you explain?

A. Yes. Because of the formation of bromotyrosine, the amount of tyrosine that shows up in the actual amino acid analysis is reduced. And this effects, of course, the ratios of all the other amino acids since they're being compared to the amount of

tyrosine.

So I've tried to show illustrate that here. So if we look at the total tyrosine content of protected co-polymer-1 -- and this is before the first HBr acetic acid deprotection step. And then if we look at the final tyrosine content for the co-polymer-1 after the second deprotection step, we see that because of the formation of the fifth amino acid, bromotyrosine, we measure substantially less tyrosine; consequently, the ratios of all the other amino acids with respect to tyrosine are elevated.

Q. All right. And we can take that down.

And, Nick, can we please go back to PTX-708T, and again I want to look at the page with the Bates number 324554.

Dr. Kent, did Mr. Konfino ever find a solution to the bromotyrosine problem?

A. Yes, he did. So this is the same paragraph that we were looking at before from Mr. Konfino's' August 1991 report. And what we see in the second paragraph, which I'll read, is that Mr. Konfino said, "Among the many reagents tried for removing the free bromine, a previous treatment of HBr acetic acid with 1 percent phenol for a few hours proved to be the most convenient."

Q. All right. And what is phenol?

A. Phenol is an aromatic alcohol.

Q. Doctor, did you help prepare demonstrative to illustrate

how the use of phenol described in Mr. Konfino's August 1991 report, addressed the bromotyrosine problem?

A. I did.

Q. All right. And, Nick, if we could take a look at the third animation, please.

And what is it that we're seeing here, Dr. Kent?

A. This again is the cover page of Mr. Konfino's August 1991 report. And we'll leaf through that and go to the same section that I've been reading from. And here we'll see highlighted the section that I should have read completely, including, "thus the bromotyrosine content is reduced or eliminated."

And here we have our animation of the copolymerization process, the four activated amino acid building blocks in water solution, with the addition of an initiator. We get the formation of the linear protected polypeptide chains, very complex mixture of millions of chains each of different amino acid sequence.

Q. And again, Doctor, at this point is this the same protected copolymer-1 one that we've seen in the previous animations?

A. This is the same protected co-polymer-1 that we've seen in the previous animations. So -- sorry.

Q. I was just going to ask, what are we going to see next; please proceed?

A. The next step is to treat with HBr and acetic acid, but in this case, it has been pretreated with phenol as Mr. Konfino

described in his August 1991 report. And you'll remember that we were getting these BRplus ions, and now the phenol reacts with those, and consequently because it's what's called an equillibrium reaction, eventually all the bromine that's present becomes BRplus, ions reacts with the phenol to be scavanged to form unreactive phenol derivatives.

Q. All right, I've got two questions. One, you used the word scavanged there. What did you mean by that?

A. Scavanged is sort of a colloquial term that chemists use to mean to remove an impurity, by mopping it up in a chemical reaction.

Q. And at this point, are the BRplus ions still reactive?

A. Oh, no, no. The reaction product here is inert under these reaction conditions.

Q. And if we can continue.

A. So now we have HBr and acetic acid that has been treated with phenol, so there's no bromine present, and now we go back to the acid deprotection step that's ongoing. It removes the protecting groups, benzyl protecting groups from the glutamic acids throughout the copolymer mixture. We end up with the TFA copolymer-1 trifluoracetyl co-polymer-1. That's treated with piperidine as before. So the side chain TFA groups from the lysine residues are removed, to give us co-polymer-1 free of bromotyrosine.

Q. If we wanted to characterize the co-polymer-1 composition

made with phenol, how would we go about doing that?
A. You would use the same amino acid hydrolysis and amino acid procedure as we've done, illustrated in the past. So we take a sample of the product mixture, we heat it with aqueous acid to convert back to amino acids. We then separate those and determine the amount of each as represented here, giving the different amounts of the four amino acids that are present in this product co-polymer-1.
Q. All right. Now, Doctor, let me ask you, is there any bromotyrosine here?
A. There's little or no bromotyrosine because of the use of phenol, the scavenger.
Q. All right. And what are the numbers beneath the test tubes, please?
A. Those are the molar ratios of the four amino acids as determined by hydrolysis and amino acid analysis.
Q. All right. And, Dr. Kent, why is the molar ratio changed here from the previous animation that we looked at?
A. As we saw, previously up to 30 percent of the tyrosine can be converted to bromotyrosine. That, in the past, reduced the amount of tyrosine that was determined in the amino acid analysis.

Here the full amount of tyrosine is present. Consequently, the ratios -- remember these are ratios. If you look at the amount of alanine relative to the tyrosine, there

are approximately 4.6 alanines for every tyrosine present in the product copolymer mixture.

Similarly, there are approximately 1.5 glutamic acids relative to tyrosine and approximately 3.6 lysines relative to tyrosine.

Q. All right. Now, Doctor, have you prepared a slide summarizing the effect of the use of phenol that we've just seen in this animation?

A. Yes, I have.

Q. And if you could just describe what we're looking at here, please, Doctor?

A. Well, what I've tried to represent here is that if we start with the protected copolymer-1 as described in the '808 patent, and on the top arrow we use HBr acetic acid containing bromine, then we end up with molar ratios of alanine, glutamic acid, lysine with respect to tyrosine of 6:2:5:1.

However, if we take precautions to make sure there is no bromine present in the HBr acetic acid reagent while treating with phenol, then we end up with amino acid ratios as shown on the bottom where there are 4.5 alanines, 1.5 glutamic acids, 3.6 lysines with respect to every one tyrosine.

Q. All right. Nick, let's take a look at PTX-708T, again, please, and I want to look at the Bates with the Bates number 324554 at the end. If we could blow up section two.

Doctor, do you see the last sentence there, where Mr.

Konfino says "The bromotyrosine was later tested and proven nontoxic?"

A. I do. This is the same section that Mr. Konfino's' report that we've just been looking at and, yes, I do see that sentence.

Q. All right. And what's your understanding of that sentence?

A. Well, it's a little bit inexact in its terminology, but I assume he's referring to bromotyrosine containing copolymer-1. And what he's stating here that it was tested and proven nontoxic.

Q. All right. Now, let me ask you -- and we can take that down, Nick. Doctor, do you know when Mr. Konfino began using phenol to remove free bromine in the HBr acetic acid solution?

A. Yes. I believe it was in the second half of 1989.

Q. All right. And how did you gain your understanding?

A. I looked at pages from Mr. Konfino's lab notebooks.

Q. All right. I'd like to look at some of Mr. Konfino's lab notebooks. And could we please put up DTX-1730, please.

All right. And, Dr. Kent, is this one of Mr. Konfino's lab notebooks that you reviewed in forming your opinions in this case?

MS. HOLLAND: Your Honor, before we go on, we had identified to us yesterday pages from the exhibits that were going to be shown publically, but there were no lab notebook pages identified. So we assumed they weren't going to be shown

publicly.

MR. ANSTAETT: Your Honor, I will say that I had conversation with Mr. Mitrokostas yesterday, who I told him that, you know, as a courtesy we would provide pages to Teva for many of the documents, but the lab notebooks we weren't going to be able to do that. He told me that it would be, assuming that they were within the scope of the expert reports, they could be shown publicly. I will say these are lab notebooks that are from 20 to 22 years old, so I'm not entirely clear what the confidentiality concern is, but if it is a problem, we could work with private screens.

MS. HOLLAND: Well, I mean I would ask that you at least tell me in advance when you're going to show, then we can make a determination since we don't know what you're going to put up yet.

MR. ANSTAETT: I'm happy to work with that, and.

THE COURT: Okay. Any problem with this one?

MS. HOLLAND: Front page, your Honor, no.

Q. And, Doctor, let me ask you, is this one of the laboratory notebooks you reviewed in forming your opinions in this case?

A. It is.

MR. ANSTAETT: Your Honor, I move admission of DTX-1730.

MS. HOLLAND: No objection.

THE COURT: Admitted.

(Plaintiff's Exhibit 1730 received in evidence)

Q. First page we're going to look at has the Bates number TEV1178554.

MS. HOLLAND: My suggestion would be to put these on the private screen.

THE COURT: All right. We can do that rather than delay things, I guess, and then will you get back to us and indicate, Ms. Holland, whether they can be public.

MS. HOLLAND: Yes, I will.

MR. ANSTAETT: Just to be clear, I'm going to ask obviously Dr. Kent questions about what appears on the page and he's going to describe them. I assume that's okay with Ms. Holland.

MS. HOLLAND: Do you mean that he's going to read in what's in the lab notebook page? That's kind of -- it defeats the purpose of putting it on the private screen.

MR. ANSTAETT: It is exactly the way we've handled everything up to this point in the case they're on the private screens, the witness are allowed to put testimony on. He's going to be making some --

THE COURT: I'm not quite sure what the issue is here. We have modified the testimony somewhat when it was necessary to leave out specific numbers, et cetera.

MS. HOLLAND: That's what I would ask, your Honor, if the testimony goes in generally without specific numbers at

this point, and perhaps after, I don't know --

MR. ANSTAETT: May I suggest Ms. Holland and I have a one to two minute conversation, maybe we can alleviate this concern?

THE COURT: Okay, sure.

MR. ANSTAETT: Thank you, your Honor.

THE COURT: Am I allowed to leave or --

MR. ANSTAETT: We'll try to do it quickly.

THE COURT: Why don't you.

(Pause)

THE COURT: Ready?

MR. ANSTAETT: Yes. Thank you, your Honor.

Q. With the -- just give Dr. Kent the guidance that maybe don't mention the specific concentration of a reagent, but everything -- I think your testimony will be fine and we will keep these on the private screens.

A. That applies only to reagents? I need to be clear on this, before I mess up.

Q. For instance, the bromotyrosine contents you would be free to discuss, or the use of particular reagents, free to discuss. So we can proceed and Ms. Holland will let us know if we're crossing any boundaries.

MS. HOLLAND: I don't anticipate any issues based on what Mr. Anstaett just told me.

THE COURT: Okay.

A. I'm still not quite clear. One more time, please?
Q. You can just -- let's proceed and if an issue arises, Ms. Holland will let us know. I don't think it will be a problem.
A. Okay.
Q. All right.

Okay. So these will be on the private screens. Nick, the first page I want to look is the one with the Bates page 1178554.

And, Dr. Kent, if you could describe for me what we are looking at on this page?
A. Yes. This is an experiment from Mr. Konfino's' lab notebook. As you can see at the top, the initials R.E. San for research, which is his first 1st name. It's actually the 6,751st experiment he's performed at Teva, minus 2,000. And it's on May the 1st, 1989, and Mr. Konfino is preparing TFA co-polymer-1 by treating blocked co-polymer-1 with HBr and acetic acid from a commercial supplier.
Q. All right. Now, on this page has the HBr acetic acid solution been treated with phenol?
A. There is no mention of phenol on this page.
Q. All right. And does Mr. Konfino note anything about the bromotyrosine content of this batch of TFA cop-1?
A. Yes. At the bottom he reports that his test for bromotyrosine was positive.
Q. All right. Nick, I want to ask you to put up the page

1178582, please.

And, Dr. Kent, what do we see here on this lab notebook page?

A. This is another experiment from Mr. Konfino's lab notebook. It's dated May the 18th, 1989. It's titled HBr acetic acid containing bromine. And in this experiment, if we go down to the third line, Mr. Konfino writes "HBr acetic acid contaminated with," and then he's inserted .2 5 percent bromine, left overnight at room temperature.

Q. All right. And Nick, if we could then turn to the page with the Bates number 1178584.

And, Dr. Kent, what do we see on this page?

A. This is another experiment from Mr. Konfino's notebook dated May the 18th, 1989. And here Mr. Konfino's preparing blocked copolymer, excuse me, TFA copolymer-1 from blocked copolymer-1. So I should explain. On some of these entries you'll see that he refers to copolymer-1 as protected copolymer-1, some as blocked copolymer-1. It's the same thing. And underneath the title of the experiment in parentheses he says bromine contaminated. So here he's using HBr and acetic acid that he has previously contaminated as we just saw, with bromine. So it contains bromine.

Q. All right. And did Mr. Konfino treat the HBr and acetic acid with phenol in this experiment?

A. He did not.

Q. All right. And did he report anything about the bromotyrosine content of this batch of TFA copolymer-1?
A. Yes. At the bottom we can see that his test for bromotyrosine and the product TFA copolymer-1 was positive.
Q. All right. Nick, if we can take a look at the page with the Bates number 1178586, please.
And what are we -- what are we looking at on this page, Dr. Kent?
A. Another experiment from Mr. Konfino's lab notebook. The date is May the 18th, 1989. And here Mr. Konfino is preparing TFA copolymer-1 from blocked copolymer-1, using HBr and acetic acid from a commercial supplier.
Q. All right. And did Mr. Konfino treat the HBr and acetic acid solution in this experiment with phenol?
A. There is no mention of phenol anywhere on this page.
Q. Did he report anything about the bromotyrosine content of this batch?
A. He did. As we can see at the bottom, he reported bromotyrosine as positive strong.
Q. We can take that notebook down, and I'd like to turn to another one, Mr. Konfino's lab notebooks. This time DTX-1736. And I think we can probably put up this page on the public screen.
Dr. Kent, just let me ask you, is this one of the Mr. Konfino's laboratory notebooks that you reviewed in preparing

your expert reports?
A. It is.
MR. ANSTAETT: And, your Honor, I move admission of DTX-1736.
MS. HOLLAND: No objection.
THE COURT: Admitted.
(Plaintiff's Exhibit 1736 received in evidence)
Q. Now, we should go back to the private screens. I want to look at the page with the Bates number 1176564.
And, Dr. Kent, what are we seeing on this page?
A. This is an experiment from Mr. Konfino's lab notebook. It's dated August the 20th or perhaps 21st, 1989. Mr. Konfino is preparing TFA copolymer-1 from blocked copolymer-1, and he's using in this first deprotection step, HBr acetic acid from commercial supplier Merck, and it says containing phenol.
Q. So Mr. Konfino is using phenol in this batch from August of 1989?
A. He is.
Q. All right. Nick, if we could turn to the page with the Bates number 1176574, please.
And, Dr. Kent what do we see on this page of Mr. Konfino's lab notebook?
A. This is dated August the 23rd, 1989. And here Mr. Konfino has taken the TFA copolymer-1 formed in the first deprotection step that we just looked at, and he's now doing a second

deprotection step removing the TFA groups with piperidine to form copolymer-1.

Q. All right. And was, just to be clear, was this batch of HBr acetic acid treated with phenol?

A. Well, this is the second deprotection step with piperidine. The TFA copolymer-1 that is being used here was formed from protected copolymer-1 using HBr acetic that had been treated with phenol.

Q. All right. And if we could turn to the next page of the lab notebook, please, that is 1176575. Did Mr. Konfino report a bromotyrosine content of this batch of copolymer-1?

A. Yes, he did. If you look at the bottom of the page here, he reports a bromotyrosine content of the product copolymer-1 as less than or equal using the mathematical symbol very low content of .1 percent.

Q. All right. Let's turn to the page with the Bates number TEV 1176730.

And, Doctor, what do we see on this page, please?

A. This is an experiment from Mr. Konfino's lab notebook. It's dated February the 14th, 1990.

Here Mr. Konfino is preparing TFA copolymer-1, excuse me, from blocked copolymer-1 using HBr and acetic acid from Merck, a commercial supplier, and it is the notation 1 percent phenol.

Q. All right. And does he, does he report anything about the

bromotyrosine content of this batch of TFA copolymer-1?
A. He does. At the bottom of the page the bromotyrosine content of the TFA copolymer-1 as reported is 0.1 percent.
Q. Let's turn to the page with the Bates number TEV 1176738. Doctor, what do we see on this page, please?
A. This is an experiment from Mr. Konfino's lab notebook dated February the 19th, 1990, in which he's preparing TFA copolymer-1 from blocked copolymer-1 using HBr and acetic acid supplied by Merck containing 1 percent phenol.
Q. All right. Does Mr. Konfino report anything about the bromotyrosine content of this batch?
A. He does. At the bottom of the page he reports bromotyrosine content as 0.1 percent.
Q. All right. We can put that lab notebook away. And I want to look at another of Mr. Konfino's lab notebooks. If we could see DTX-1679.
Dr. Kent, is this another one of Mr. Konfino's laboratory notebooks you reviewed in preparing your reports?
A. It is.
MR. ANSTAETT: Your Honor, I move admission of DTX-1679?
MS. HOLLAND: No objection.
THE COURT: Admitted.
(Plaintiff's Exhibit 1679 received in evidence)
Q. Dr. Kent, if we look now at the page with the Bates number

1176791, please. What do we see on this page?
A. This is another experiment from Mr. Konfino's lab notebook dated March the 6th, 1990, in which Mr. Konfino is preparing TFA copolymer-1 from protected copolymer-1, using HBr acetic acid from Merck, plus 1 percent phenol.
Q. And what does he report about the bromotyrosine content of this batch of TFA cop-1?
A. At the bottom of the page it reports the bromotyrosine content as less than 0.1 percent.
Q. All right. Let's look at the page with the Bates number 1176877, please. Dr. Kent, what are we looking at on this page?
A. This is May the 6th, 1990, another experiment from Mr. Konfino's lab notebook, in which he's preparing a TFA copolymer-1 from protected copolymer-1. He's using HBr acetic acid, plus 1 percent weight volume phenol.
Q. And does he report anything about the bromotyrosine content of this batch?
A. He does. It says at the bottom, check for bromotyrosine, and then the mathematical symbol for less than or equal to 0.1 percent.
Q. All right. Let's turn to the page with the Bates number 1176989, please. Doctor, what do we see here?
A. This is an experiment from Mr. Konfino's lab notebook dated July the 16th, 1990, in which Mr. Konfino's preparing TFA

copolymer-1 from protected copolymer-1. And as we can see in the sub title he says, adhere to BY, that's Bio-Yeda, procedure as close as possible.

Q. All right. And when he is making this batch, is he using phenol to pre-treat the HBr acetic acid solution?

A. No. He says HBr acetic from BDH, which is the commercial supplier. There's no mention of phenol on this page.

Q. What does Mr. Konfino report about the bromotyrosine content of this batch?

A. At the bottom of the page you can see that he has bromotyrosine, and then mathematical symbol for much greater than 0.5 percent.

Q. All right. And in your opinion, what is the much greater than .05 percent of bromotyrosine result attributable to here?

A. Well, apparently, the HBr acetic acid from the commercial supplier BDH must have contained bromine as impurity.

Q. And what does that result in?

A. That led to the formation of bromotyrosine in the product copolymer chains.

Q. All right. Let's turn to the page with the Bates number 1177179. And what do we see here on this page of Mr. Konfino's lab notebooks?

A. This is November the 11th, 1990, at page from Mr. Konfino's lab notebook in which he describes the preparation of TFA co-polymer-1 from protected copolymer-1 using HBr acetic acid

containing 1 percent phenol.

Q. So we're back to the use of phenol in the preparation of the HBr acetic acid solution?

A. That's correct.

Q. What does Mr. Konfino report about the bromotyrosine content, please?

A. At the bottom of the page he describes the bromotyrosine content of the polymer as less than 0.1 percent.

Q. All right. We can put that lab notebook away.

I want to look at one more of Mr. Konfino's lab notebooks, PTX-52T.

And, Dr. Kent, is this another one of Mr. Konfino's laboratory notebooks that you reviewed in preparing your reports?

A. It is.

(Continued on next page)

MR. ANSTAETT: Your Honor, I would move admission of DTX 52T.

MS. HOLLAND: No objection.

THE COURT: Admitted.

(Defendant's Exhibit DTX 52T received in evidence)

Q. Turn to the page with the Bates number 1177256, please and what do we see on this page, Dr. Kent?

A. We see an experiment dated something January, I think, the 7, 1991, in which Mr. Konfino is comparing TFA copolymer-1 from protected copolymer-1 using HBL acetic acid containing 1 percent white volume phenol.

Q. Does he report a bromotyrosine content for this batch of copolymer-1?

A. Yes, at the bottom of the page he simply says bromotyrosine less than .15 percent.

Q. Thank you very much. And we can take that down.

Doctor, have we discussed all the examples from Mr. Konfino's laboratory notebooks in which he used phenol to treat the HBr acetic acid solution and reported a low bromotyrosine content?

A. No. There were many examples from Mr. Konfino's laboratory notebooks.

Q. Did you note a pattern in his laboratory notebooks?

A. I did. As I looked through his notebooks from starting from about the middle of 1989 through to the early part of 1991

I noticed Mr. Konfino used the pretreatment of HBr acetic acid with phenol with increasing frequency and the number of experiments in which he just used commercial HBr with acetic acid decreased in frequency.

Q. Did Mr. Konfino always use phenol in his experiments?

A. No, he did not.

Q. If we could look at DTX 52T again on the private screens and I want to look at the page with the Bates number 1177354. What is your understanding of what's being reported on this page, please?

A. This is an experiment in Mr. Konfino's laboratory notebook from March 10, 1991 in which Mr. Konfino is comparing TFA copolymer-1 from protected copolymer-1 and he's using HBr acetic acid from the commercial supplier Merck.

Q. If we look at the next page ending in 75, did he achieve a low bromotyrosine content?

A. He did. He reports at the bottom of the page the bromotyrosine content is less than .5 percent.

Q. Following this experiment on March 10, 1991, did Mr. Konfino ever use phenol again in preparing TFA copolymer-1?

A. Yes, he did.

Q. If we could see the page with the Bates number 1177384, please? And what do we see here?

A. This is an experiment from March 19, 1991 in which Mr. Konfino is preparing TFA copolymer-1 from protected copolymer-1

using HBr acetic acid plus 1 percent phenol.
Q. After March 1991 did Mr. Konfino author any reports in which he mentioned the use of phenol?
A. Yes. As we've already seen the August 1991 report from Mr. Konfino reports the use of phenol for treating the HBr acetic acid for the first deprotection stage.
Q. Just to be clear if we could bring up PTX 708T? That could be on the public screen. Is this the August 1991 Konfino report that you were referring to?
A. Can we see the cover of it, please?
Q. If we go to the second page?
A. Yes. That's the one.
Q. Now, when did Mr. Konfino leave Teva?
A. It's my understanding that he retired from Teva at the end of 1991.
Q. Have you ever seen any lab notebook or report after August 1991 indicating that Mr. Konfino no longer believed that phenol was the most convenient reagent for getting rid of bromotyrosine in copolymer-1?
A. I've not seen any documents from Mr. Konfino in that time period that indicated that he changed his mind about the use of phenol in pretreating the HBr acetic acid in the first deprotection stage.
Q. According to his lab notebooks, about when did Mr. Konfino begin using phenol to beginning making low bromotyrosine

copolymer-1?
A. The beginning of 1989.
Q. Did you view any documents after 1989 that indicated that Teva made low bromotyrosine copolymer-1 without using phenol while Mr. Konfino was at Teva?
A. Yes, I did.
MR. ANSTAETT: Your Honor, this is a document I believe you'll remember well from July, although we're talking about different pages here and I believe these should be on the private screen.
THE COURT: All right, thank you.
Q. I want to take a look at DTX 999A, please and if we can look at the Bates number 1222365-RC. Dr. Kent, what are we looking at here?
A. This is a Teva Pharmaceuticals internal document describing the manufacturing procedure of cop-1, copolymer-1 for injection. It's dated December 1989.
Q. And was Mr. Konfino still at Teva in December of 1989?
A. He was.
Q. And do you see the name D. Leonov in the top left-hand corner?
A. I do.
Q. Who is that?
A. Dr. Leonov was Mr. Konfino's boss.
Q. I want to turn to the page, now, again on the private

screens with the Bates number TEV 1222382-RC. Dr. Kent, what do we see on this page?
A. This is the stage of the production of copolymer-1 on which trifluoroacetyl copolymer-1 is produced from protected copolymer-1 and I'll read the first sentence. "Hydrobromic acid 33 percent in acetic acid 5 liters is treated with phenol 50 grams for 7 to 8 hours at 20 to 25 degrees celsius. So they're describing the use of HBr acetic pretreated with phenol for the first deprotection stage.
Q. Dr. Kent, I'm going to ask you to look at a document DTX 1271, please, and this I believe to be on the public screens. And if we look at the first page of the document here, we have, is this one of the documents you reviewed in preparing your expert reports?
A. It is.
MR. ANSTAETT: Your Honor, I would move admission of DTX 1271.
MS. HOLLAND: No objection.
THE COURT: Admitted.
(Defendant's Exhibit DTX 1271 received in evidence)
Q. What are we looking at here, Dr. Kent?
A. This is a validation report prepared or co-authored by Mr. Konfino and it's dated June 1990.
Q. If we could turn to the page with the Bates number 324714, please? If we can make that a little larger? What do we see

on this page, please, Dr. Kent?
A. Could we include the heading, please? Thank you. Yes, what Mr. Konfino is describing and his co-author are describing in this report is the conversion of protected copolymer-1 to TFA copolymer-1 and in the first sentence, which I'll read, he says, "Phenol AR" -- stands for analytical reagent -- "1.5 grams was added to 152 mils," should be HBI, there's a typo -- "Acetic acid that is 33 percent HBr and stirred for about two hours at room temperature to dissolve."

The next sentence says, "The solution was stored for a total of 24 hours before use," and then they go ahead and use it in the first deprotection step.
Q. Does Mr. Konfino report anything about the bromotyrosine content from this batch?
A. Yes. If we look at the bottom of the highlighted region we see the bromotyrosine content was reported as less than .1 percent.
Q. Doctor, did you read Mr. Konfino's deposition transcripts?
A. I did.
Q. So you're aware that Mr. Konfino testified that phenol was not used in Teva's manufacturing process?
A. I am aware that Mr. Konfino testified at his deposition that phenol was not used in Teva's manufacturing process.
Q. Do you agree that Teva did not use phenol in its manufacturing process?

MS. HOLLAND: Your Honor, I'm sorry. Mylan didn't designate any of Mr. Konfino's deposition testimony and I don't believe the representations about what he said were exactly right.

MR. ANSTAETT: Your Honor, there was obviously an issue with bringing Mr. Konfino. More importantly, Dr. Kent made this exact observation in his expert reports that were served ages ago.

THE COURT: All right. If the characterization was incorrect, I'll certainly take a look at that, but go ahead, give us your opinion, Doctor.

Q. Thank you. So the question, again, was did you agree that Teva did not use phenol in its manufacturing process while Mr. Konfino was at Teva?

A. Teva did use phenol in its manufacturing process based on the documents I've examined while Mr. Konfino was still at Teva.

Q. All right. Doctor, I'm going to ask you to look at DTX 1270, and is this a document that you reviewed in preparing your expert reports, please?

A. This is one of the documents I reviewed, yes.

MR. ANSTAETT: Your Honor, I would move admission of DTX 1270.

MS. HOLLAND: No objection.

THE COURT: Admitted.

(Defendant's Exhibit 1270 received in evidence)

Q. Doctor Kent, what are we looking at here?

A. This is a Teva annual review report for the manufacture of copolymer-1 in the period 1991 to 1992, and it's dated January, 1993.

Q. All right. Was Mr. Konfino at Teva in 1991?

A. Mr. Konfino was at Teva through the end of 1991.

Q. Let's look at the page with the Bates number TEV 3017396, please. And, Doctor, I'm going to ask you under "introduction" to read the first two sentences.

A. Yes. The first two sentences of this introduction read as follows: "Cop-1, copolymer-1 has been manufactured in a specially designed unit at Plantex starting from mid-1989. In the subsequent 18 months, several changes were made enabling safer production, better and more efficient operating conditions and better quality.

Q. And does one of the changes relate to the use of phenol?

A. Yes, it does. If we look a little bit low, we see the heading, "The major improvements are as follows: " And then one says something about polymerization time, number two talks about using water instead of diethylether and the third major improvement, and I'll read the section is, "HBr acetic acid is pretreated with phenol before use, thus preventing side reaction of free residual bromine with a tyrosine moiety."

Q. Is this the same pretreatment that you previously described

being used by Mr. Konfino?
A. It is the same phenol pretreatment used by Mr. Konfino, yes.
Q. I'd like you to turn to the page with the Bates number 309792 and 793, please.
Q. Let's focus first on 7972. Doctor, what is the title of this table?
A. This table 10 is entitled TFA cop-1 manufacturing performance 1991 to 1992 quality and quantity.
Q. And what is shown in the left column, please?
A. This is the first 30, or listed by number the first 30 of the production batches of the 49 that are present in the entire table.
Q. And what does the table show with respect to bromotyrosine?
A. Well, we can see if we go across towards the right that there's a column that's titled bromotyrosine content and in parenthesis is the specification they're trying to meet, less than or equal to .5 percent, and then across from each of the 30 lots you see mostly we see passes.
Q. All right, and are they all passes?
A. No. There's two down in the middle section, about 12 and 13, I think, where one says greater than 0.5 and the other says greater than or equal to 0.5 and if we look over on the right in the notes column, we see that these two batches were rejected.

Q. All right. Now, Doctor, let me ask you, could Teva have fixed those two batches of copolymer-1 by simply purifying out the bromotyrosine?
A. No. The bromotyrosine that's formed is an integral part of the copolymer chains, and there's no known fractionation procedure that could remove the bromotyrosine from the copolymer chain product. It's built into it.
Q. And would the same be true of bromotyrosine if it occurred in Mylan's product, could it simply be purified out?
A. If there were a bromotyrosine impurity in any preparation of copolymer-1, clearly Mylan's product, then no, it could not be purified out.
Q. And, Dr. Kent, are there additional documents that you reviewed that indicate that Teva continued to make low bromotyrosine copolymer-1 using phenol even after Mr. Konfino left Teva?
A. Yes, there are.
Q. And here I want to be mindful of the confidentiality issues. I want to look at just on the private screens DTX 1023, please.
MR. ANSTAETT: And, your Honor, this document was admitted during Dr. Pinchasi's testimony in July.
THE COURT: All right.
Q. Doctor, is this a document you reviewed in preparing your expert report?

A. Yes, it is. It's part of Teva's NDA application.
Q. When did Teva submit its NDA to the FDA?
A. I think they submitted this NDA for Copaxone copolymer-1 in 1995.
Q. Let's look at the page with the Bates number TEV 541, please. And, Doctor, what do we see on this page?
A. This is a description of the step that's involved in converting protected copolymer-1 to TFA copolymer-1, and I'll read the first sentence: It says, "Protected copolymer-1, 4 kilograms is dissolved in 108 kilograms of a solution of 33 percent hydrogen bromide in acetic acid (previously treated with phenol to remove free bromine which may react with tyrosine residues leading to bromotyrosine residue impurities) and stirred at 26 plus or minus 1 degree celsius in a glass-lined reactor for the amount of time determined by the test reaction (note 1)."
Q. So Teva told the FDA that it used phenol in its manufacturing process for making Copaxone?
A. It did. That's what's in this document, yes.
Q. Was the use of phenol disclosed in any of the patents in suit?
A. It is not disclosed in any of the patents in suit.
Q. Doctor Kent, in your opinion is using phenol to reduce the bromotyrosine in copolymer-1 a routine detail that would have been apparent to anyone of skill in the art in 1994?

A. No, in my opinion it would not have been a routine detail for one of normal skill in the art for 1994.
Q. Have you seen any documents indicating whether the Weizmann Institute scientists recognized the problem of bromotyrosine formation in copolymer-1?
A. I've seen no document that suggested that the Weizmann scientists had recognized the problem with bromotyrosine copolymer-1.
Q. Dr. Kent, did Teva obtain any patents on the process of using phenol to eliminate bromotyrosine in copolymer-1?
A. Yes, they did.
Q. Could we see DTX 1925, please? And, Dr. Kent, is this one of the patents that you reviewed?
A. Yes, it is.
Q. And to be clear, is this one of the patents in suit?
A. No, it is not one of the patents in suit.
Q. And to whom is the patent assigned?
A. It's assigned to Teva Pharmaceutical Industries, Ltd.
Q. And what is the name of the inventor?
A. The name of the inventor is Ben-Zion Dolitzky.
Q. When is it applied for?
A. It was applied, it was filed on September 9, 2005. I think it claims an earlier priority date. Yes, 2004.
Q. Do you see the provisional application down there? What's the date on that?

A. I'm sorry?
Q. What's the date, I think you just mentioned it.
A. September 9, 2004.
Q. Thank you. And when did the patent issue?
A. The patent issued February 24, 2009.
Q. And what according to the title does it cover?
A. The title reads a process for preparation of mixtures of polypeptides using purified hydrobromic acid.
MR. ANSTAETT: Your Honor, I move admission of DTX 1925.
MS. HOLLAND: No objection.
THE COURT: Admitted.
(Defendant's Exhibit DTX 1925 received in evidence)
MR. ANSTAETT: Nick, if we could go into the specification and look at column 1, lines 47 to 67 and column 2, lines 1 to 17.
Q. And, Dr. Kent, what is being discussed in the sections that we're looking at here?
A. This part of the patent specification of the Dolitzky patent in the first sentence, which I'll read, describes, "The manufacturing process as detailed in the above patents involves reacting protected polypeptides with 33 percent hydrobromic acid in acetic acid," and then it cites U.S. Patent No. 5800808 issued September 1, 1998 to Konfino, et al. It's the '808 patent.

Q. Is that one of the patents in suit?
A. It is one of the patents in suit.
Q. If we look down at the bottom of the excerpt here how is the invention disclosed in the Dolitzky patent that we're looking at here described?
A. The invention was, it says at the bottom, "this invention provides an improved manufacturing process."
Q. And, Nick, I'm going to ask you now to put up column 9, lines 36 to 58 of the Dolitzky patent on one side of the screen, and on the other side of the screen I'd like to see PTX 708T, which is Mr. Konfino's August 1998 memo. What are we looking at here, Doctor?
A. On the left is part of the patent specification for the Dolitzky patent, the phenol patents and on the right is part of Mr. Konfino's August 1991 report.
Q. All right, and what do we see in the two blue action boxes, please, if you start on the left with Dolitsky patent?
A. On the left in the Dolitsky patent we see the sentence highlighted, "For example, during the development of the production process for GA" -- GA is glatiramer acetate -- "it was found that some of the tyrosine residues in trifluoroacetyl GA and in the GA were brominated," and on the right in the blue box from Mr. Konfino's report is stated, "Still in an early stage of work. One of the impurities of cop-1 was identified as bromotyrosine."

Q. All right, and I'll ask you to do the same thing for the green boxes, please.
A. Yes, in the Dolitzky patent on the left, we see the sentence: "After much investigation, the inventors discovered that the brominated tyrosine impurity was introduced into the GA through free bromine in HBr acetic acid," and in the corresponding green box on the right in Mr. Konfino's report, we see the presence of small amounts of -- we should actually go a little bit above. "It was then proven that the presence of the small amounts of free bromine in the HBr acetic are to be blamed for the small amount of impurities."
Q. If we could do the same thing for the red boxes, please?
A. Yes. On the left in the Dolitzky patent we see highlighted, "For example, pretreatment of HBr acetic acid with a bromine scavenger was effective in removing some of the free bromine from the HBr acetic acid solution. One of the bromine scavengers used in the HBr purification pros was phenol."
And in the corresponding red box on the right in Mr. Konfino's report, we see, "Among the many reagents tried for removing the free bromine, a previous treatment of HBr acetic acid with 1 percent phenol for a few hours proved to be the most convenient."
Q. All right. Now, Dr. Kent, in your opinion, how does the process described in this portion of the Dolitzky patent relate to what Mr. Konfino described in his August 1991 report?

A. They're essentially identical.
Q. I want to look at the claims of the Dolitzky patent now, and if we could highlight claims 3 to 7, column 14, please. Dr. Kent what is your understanding of what is being described in claim 3?
A. In claim 3, as I'll read, what is claimed is a process of producing glatiramer acetate comprising the steps of, and then in step one, treating a solution of hydrobromic acid in acetic acid with a bromine scavenger so as to prepare a treated hydrobromic acid in acetic acid solution.

Then in step two it describes the polymerization reaction, step 2A, and step 2B I'll read that out, "deprotecting protected polypeptides with the treated hydrobromic acid in acetic acid solution prepared in part 1 to form trifluoroacetyl glatiramer acetate." And then what's claimed, what's described in claim 3 is step C and D that are the TFA removal with piperdine and then purifying the product glatiramer acetate.
Q. All right, and what is your understanding of what's being described in claim 7, please?
A. Claim 7 describes the process of claim 3, wherein the bromine scavenger is phenol.
Q. Dr. Kent, how does the process claimed here compare to what Mr. Konfino reported in his August 1991 report?
A. They're essentially identical.

Q. This patent was not filed until 2004, is that correct?
A. That's correct.
MR. ANSTAETT: If we could take that down. Your Honor, I am at a transition point. I don't know how you feel about --
THE COURT: All right. It's almost 1:00 so we'll adjourn for lunch. I'll see everybody at 2.
(Luncheon recess)
o0o
AFTERNOON SESSION
2:05 p.m.
THE COURT: You may proceed.
MR. ANSTAETT: Thank you, your Honor.
BY MR. ANSTAETT:
Q. Look at DTX 1225. Dr. Kent, before lunch we were talking about the Dolitzky patent. I just have one more question for you on that. If we could see column 1 of the patent, lines 12 through 33, starting with the background of the invention. I'm just going to ask you to read the first sentence of background of the invention, please.
A. A mixture of polypeptides which do not all have the same amino acid sequence referred to as glatiramer acetate, GA, is marketed under the trademark Copaxone, registered trademark, and comprises the acetate salts of polypeptides containing L-glutamic acid, L-alanine, L-tyrosine and L-lysine at average

molecular fractions of 0.141, 0.427, 0.095 and 0.338, respectively.

Q. And so the Dolitzky patent reports the molar fractions, the average molar fractions for Copaxone?

A. It does.

Q. We can take that down.

Dr. Kent, I now want to talk about the claims of the patents in suit. Did your infringement analysis, your non-infringement analysis focus on a particular claim term?

A. Yes, it did. I focused on the claim term copolymer-1 that appears on all the claims of the patents in suit.

Q. If we could look at the Court's claim construction, please. Dr. Kent, what are we looking at here?

A. I understand this is the Court's definition or agreed definition of copolymer-1.

Q. And in your opinion, is Mylan's proposed glatiramer acetate product composed of alanine, glutamic acid, lysine and tyrosine in a molar ratio of approximately 6:2:5:1 respectively?

A. In my opinion, Mylan's proposed glatiramer acetate product is not composed of alanine, glutamic acid, lysine and tyrosine in a molar ratio of 6:2:5:1.

Q. What would a molar ratio of 6:2:5:1 tell you about the amino acids in copolymer?

A. What you're talking about is six alanines for every one tyrosine approximately; approximately two glutamic acids for

every one tyrosine, and approximately one lysine for every five tyrosines.

Q. Did you determine the molar rations for Mylan's proposed product?

A. I did.

Q. How did you go about doing that?

A. I looked at Mylan's ANDA, I believe.

Q. All right, and does Mylan's ANDA report the molar fractions for its product?

A. It does.

Q. And what are molar fractions?

A. Molar fractions are the primary data that you get from amino acid analysis so you hydrolize your sample, you determine the amount of each amino acid and then that is usually reported as molar fractions. By definition they add up to one.

Q. Let's look at PTX 294R, please.

MR. ANSTAETT: And, your Honor, PTX 294R is in evidence, I believe. Out of an abundance of cause of action I would move that into evidence.

THE COURT: All right.

(Plaintiff's Exhibit PTX 249R received in evidence)

Q. Dr. Kent, is this one of the certificates, the Mylan certificates of analysis that you reviewed?

A. Yes, I believe it is.

Q. And if we could see, I want to direct your attention to

Section 8 of the certificate, please. And what do we see here?
A. Section 8 is a list of the amino acids that are glutamic acid, alanine, tyrosine and lysine and on the right we see the molar fractions of each amino acid. In this case 0.144, 0.427, 0.092 and 0.336.
Q. Dr. Kent, did you prepare a demonstrative exhibit to show how you would convert the molar fractions to a molar ratio?
A. I did.
Q. Nick, if we could see the Mylan molar ratio demonstrative, please? Dr. Kent, what do we see here?
A. We're looking at the page that we just saw a moment ago with the same Section 8 highlighted. So these are the molar fractions that are reported for this batch of Mylan's proposed product. And what we'll do now is call out the molar fractions into the tabular form below, so a molar fraction of glutamic acid is 0.144; for alanine the molar fraction is 0.427, for tyrosine the molar fraction is 0.092 and for lysine the molar fraction is 0.336.

Now, to convert these into molar fractions by definition they have to be a ratio to some amino acid and commonly one uses the least abundant amino acid, in this case tyrosine. You divide by 0.092 all the way through and you end up with the molar ratio shown on the bottom line.
Q. And is this the molar ratio for this batch of Mylan's proposed glatiramer acetate product?

A. Yes, it is.
Q. And what does this molar ratio tell you about the four amino acids present in this batch of Mylan's proposed product?
A. What it tells you, the molar ratio tells you that on average there are about 4.6 alanines for every one tyrosine. On average 1.6 glutamic acids for every 1 tyrosine and on average 3.7 lysines for every one tyrosine.
Q. Would a person of ordinary skill in the art reading the patents in suit in 1994 believe that a molar ratio of 4.6 to 1.6 to 3.7 to 1.0 was approximately 6:2:5:1?
A. A person of ordinary skill in the art would not think that this molar ratio of 4.6 to 1.6 to 3.7 to 1.0 is approximately 6:2:5:1.
Q. Dr., what about the fact that the patents use the term approximately 6:2:5:1? How does the use of the word "approximately" affect your analysis?
A. Well, I understand the use of the word "approximately" to reflect the possibility of batch-to-batch variation and also the uncertainty in determining the amino acid composition, experimental uncertainty.
Q. What do you mean by batch-to-batch uncertainty?
A. When you carry out a process of random copolymerization such as is used to make the glatiramer acetate or the copolymer-1, you won't get exactly, even if you try to control all the conditions, you won't get exactly the same product

composition, it's too complex of a product mixture. So you'll get some small batch-to-batch variation, and in addition, the determination of how much of amino acids is in each batch will also have an experimental uncertainty associated with it.

Q. I want to talk about experimental uncertainty. In 1994 what would a person of ordinary skill in the art conducting an amino acid analysis have expected in terms of experimental uncertainty?

A. For amino acid analysis?

Q. Yes.

A. A person of ordinary skill in the art in the 1994 for amino acid analysis for a copolymer polypeptide composition of this type would have expected to get reproducibility of experimental uncertainty of less than 5 percent for each amino acid.

Q. And how would that experimental uncertainty affect your comparison of two copolymer-1 compositions?

A. Well, why that's commonly done to decide whether or not, if you take two samples of two compositions and you want to know based on the amino acid analysis whether they're reliably the same or reliably different, you'll take into account the experimental uncertainty in determining the amino acid analysis, and then the math of the particulars of the statistical treatment kind of complicate it, but if we regard the experimental uncertainty as a standard deviation, the common cutoff is twice the standard deviation. So in this case

if each amino acid or any amino acid between the two compositions differed by more than plus or minus 10 percent, then you would think that they were different. If the values were within, for each amino acid were within plus or minus 10 percent, you would consider them probably the same.

Q. And just to be clear, do you make that comparison for each individual amino acid in a composition?

A. We do.

Q. Now, Dr. Kent, let me ask you, did you review certificates of analysis for different lots of Mylan's glatiramer acetate product?

A. I did.

Q. If we could get indict 325R, please, and we could turn to the page with the Bates number MYL 1068. Dr. Kent, is this one of the certificates of analysis, Mylan certificates of analysis that you reviewed?

A. Yes, it's the 002, yes.

MR. ANSTAETT: And, your Honor, I believe this is an Exhibit 325R, this is also in evidence.

THE COURT: Yes, thank you.

Q. And I want to stay in the same document and ask us to look at MYL 1079. Dr. Kent, is this another one of the certificates of analysis that you reviewed?

A. Yes, this is for lot number 003.

Q. Now, did you prepare an exhibit to show the molecular

ratios of these additional lots?
A. I did.
Q. If we could see the Mylan drug substance demonstrative. And, Dr. Kent, what are we looking at in this exhibit, please?
A. Well, listed down the left-hand side under the heading Mylan lot number are the three lots that we've just seen the certificates of analysis for, and listed across the molecular ratios of the four amino acids comprising these different lots. In the row at the bottom that's labeled mean (SD), these are the mean or the average of the three numbers above. So for the alanine column the mean is 4.71 and the number in parenthesis is the experimental uncertainty that we were talking about. In this case it's about 0.06. The same applies to the other amino acids here.
Q. All right. Doctor, would a person of ordinary skill in the art reading the patents in suit in 1994 believe that any of these molar ratios was approximately 6:2:5:1?
A. No, they would not. The way you would make the number by number comparison is plus or minus 10 percent on, say, the alanine ratio of six to one, six plus or minus 10 percent would take it all the way down to 5.4, but if you looked at the alanine here and take twice the standard deviation, that's only going to take it up to 4.83, so these are significantly different numbers.
The same type of analysis applies to the glutamic

acids and the lysines, and I should point out that the, even though it looks as if tyrosine has no experimental uncertainty, that's not the case. Because these are ratios, experimental uncertainty and the amount of tyrosine, the experimental uncertainty of, say, alanine, are combined in the 0.06.

Q. The experimental uncertainty for alanine?

A. Exactly, yes.

Q. Dr. Kent, did you also determine the molar ratio of the injection batches described in Mylan's ANDA?

A. Yes, I did.

Q. If we could take a look at PTX 300R, please?

MR. ANSTAETT: And your Honor, PTX 300R is another document that is in evidence.

Q. Doctor, is this one of the certificates of analysis for the injection batches that you reviewed?

A. Yes, it's WV901.

Q. And we can take a look now at PTX 312-R, please? And same question, Dr. Kent, is this one of the certificates of analysis for the injection batches that you reviewed?

A. Yes, this was for batch number WV902.

MR. ANSTAETT: Your Honor, I believe PTX 312R is also in evidence.

Q. Finally, if we look at PTX 313R, please, Doctor, is this another one of the certificates of analysis for the Mylan injection batches that you reviewed?

A. Yes, it is. It's batch number WV903.
Q. All right. And did you prepare an exhibit to show the molar ratios of the Mylan injection batches?
A. I did.
MR. ANSTAETT: Nick, if we could see that?
Q. What do we see here, Dr. Kent?
A. This table is laid out exactly the same way as for the super ingredient Mylan batches, the glatiramer acetate batches. So down the left we have the code numbers for the three different injection batches. Across the top we have the four amino acids and again at the bottom, we have the means, mean values for each amino acid combined with the experimental uncertainty.
Q. All right. And would a person of ordinary skill in the art reading the patents in suit in 1994 believe that any of the injection batch molar ratios was approximately 6:2:5:1?
A. No, they would not, and this is most vividly demonstrated if we focus in on the lysine value. So at the bottom we see an unusually low standard deviation, I prefer to call that .06 as we did for some of the other amino acids, and if we take twice the value of .06, that will give us 3.58 for the maximum ratio of lysine to tyrosine. This is significant, very significantly different than the ratio of five to one.
Q. Dr. Kent, we've been talking about Mylan product and I want to shift gears here and talk about Teva's commercial product,

Copaxone. Did you also calculate the amino acid molar ratio of Teva's Copaxone?

A. I did.

Q. And how did you do that?

A. I used the Copaxone package insert.

Q. If we could take a look at PTX 697, please.

MR. ANSTAETT: Your Honor, this was an exhibit that was admitted in Mr. Congleton's examination.

THE COURT: Thank you.

Q. If we could turn to page 4 please, look at section 11. And what do we see here, please, Dr. Kent? Well, actually let me take a step back. Is this the Copaxone package insert that you reviewed?

A. Yes, it is. And what you see here in section 11 is the description of the Copaxone product. It outlines that that's the brand name for glatiramer acetate formerly known as copolymer-1, and then below that it gives the molar fractions that are found in Copaxone for each of the four amino acids; glutamic acid, alanine, tyrosine and lysine. So it states that the average molar fractions are 0.141 for glutamic acid, .427 for alanine, .095 for tyrosine and .338 for lysine.

Q. Doctor, did you prepare an exhibit to show how you calculate the molar ratios for Copaxone?

A. I did.

Q. If we could see the Copaxone demonstrative, please.

A. So this is the Copaxone package insert and we're going through to section 11 and we've highlighted here the same section that I just read from. And here we have the molar ratios, average molar fractions, excuse me, of Copaxone, amino acids in Copaxone and we'll call these out into the same format as we were considering earlier. So there is a glutamic acid molar fraction of 0.141, an alanine molar fraction of 0.427, a tyrosine molar fraction of 0.095, and a lysine molar fraction of 0.338, and of course by definition fractions add up to one.

The molar ratios are calculated in the conventional manner, dividing through by the molar fraction of the least abundant amino acid, in this case tyrosine 0.095. If you do that for each molar fraction, you get the numbers shown on the bottom line. These are the molar ratios of the amino acids found in Teva's Copaxone.

Q. And what does this molar ratio tell you about the amino acid composition of Copaxone?

A. What it tells me is that the Copaxone product composition contains on average 4.6 alanines for every one tyrosine, 1.5 glutamic acids for every one tyrosine and 3.6 lysines for every one tyrosine.

Q. And why aren't these whole numbers, Dr. Kent?

A. Well, the copolymer-1 Copaxone polypeptide product mixture is such a complex mixture of polypeptides of different amino acid sequence, there's no expectation that these will

necessarily occur in whole number ratios. The ratios are determined by the molar fractions, determined by amino acid analysis and they are what they are as shown here.

Q. All right. Now, Doctor, preparing your expert reports did you come across any publications in which the molar ratio of Teva's glatiramer acetate product had been calculated?

A. I did.

Q. If you could look at DTX 1685, please, and, your Honor, this was admitted in Dr. Gokel's cross-examination.

THE COURT: Thank you.

Q. Dr. Kent, is this the patent you reviewed?

A. It is.

Q. And what is the title?

A. And the title of the patent is copolymer-1 related polypeptides for use as molecular weight markers and for therapeutic use.

Q. Who is it assigned to?

A. It's assigned to Yeda Research and Development Company.

Q. Do you recognize that as the name of one of the plaintiffs in this case along with Teva?

A. I do.

Q. Does this patent describe both the mole fractions and the mole ratio of the amino acids in glatiramer acetate?

A. Yes. This Gad patent does describe both the mole fractions and the mole ratios for the glatiramer acetate.

Q. Did you prepare a demonstrative exhibit showing how in your calculation the calculation of the molar ratio in the '287 patent was performed?
A. I have.
Q. Could we have that, please? What are we looking at here, Doctor?
A. That's the front page of the Gad '287 patent. We're going into the part of the specification that shows the molar ratio and molar fractions. As you can see highlighted here towards the bottom of this section, it says the molar fractions are approximately 0.427, etc., and we're going to call those out into the same format as we've been using up till now. So .427 for alanine, .141 molar fraction for glutamic acid, 0.337 for lysine, and 0.093 for tyrosine. So to convert these to molar ratios, I would divide by the molar fraction of the least abundant amino acid, namely tyrosine .093, so each of the molar fractions are divided by that number to give me the molar ratios shown on the bottom line and highlighted in yellow. And you can see, these numbers are identical to the ones that are present in the patent specification and the section highlighted on the paragraph shown.
Q. So in this patent, the molar ratio has been calculated in the same way that you have calculated the molar ratio for the Mylan product, is it fair to say?
A. That's correct.

Q. Is the molar ratio that is reported in this patent normalized to tyrosine?
A. You could say normalized to tyrosine. The phrase normalized is shorthand for you're reporting a ratio, which amino acid did you use as the basis for that ratio, and in my calculations and in this patent they've used tyrosine and ratioed everything else to that, including tyrosine, which is why it turns out as 1.0.
Q. If we could look again at DTX 1685, please, and I want to look at column 2, lines 46 through 55. Is there anything else from the Gad 287 patent that relates to your analysis, Dr. Kent?
A. Yes. If we look a little bit further down the same section below the molar fractions, we see after the tyrosine value the words, "and may vary by about plus or minus 10 percent." And this is in line with my analysis of one of normal skill in the art would expect, including both batch-to-batch variation and experimental uncertainty.
Q. Dr. Kent, did Teva report specifications for the individual molar fractions for its product in its NDA?
A. It did.
Q. We're going to use the private screens here now, Nick, please.
I want to look again at DTX 1023, which we looked at earlier, and which is now in evidence. And this time I want to

look at page TEV 526.

And what do we see here, Dr. Kent?

A. Well, this is part of Teva's NDA. This is a certificate of analysis for a particular batch of their copolymer-1 Copaxone, and in section 7, we see listed the amino acid content, amino acid molar fraction for four amino acids; glutamic acid, alanine, tyrosine and lysine, and on the right under results, we see the molar fractions determined for this particular batch, .144, .431, .095.331.

(Continued next page)

Q. All right. Now, what is the specification for the tyrosine molar fraction?
A. Well, if we look over to the left we can see that next to tyrosine in parentheses is the Teva specification 0.086 to 0.100 for the tyrosine molar fraction in Copaxone.
Q. All right. And would a copolymer-1 composition with a molar ratio of exactly 6:2:5:1 have a tyrosine molar fraction that falls within the Teva specification for tyrosine?
A. No, it would not. As Dr. Gokel told us in his testimony, a copolymer-1 of exact composition, excuse me, with molar ratios of exactly 6:2:5:1 would have a tyrosine molar fraction of .071, and that's well outside the lower end of the range shown on the Teva specifications.
Q. All right. Now, we can take that down, Nick, and I want to shift back to Mylan's product.

Dr. Gokel calculated a molar ratio for Mylan's product of 5.98:2.02:4.70:1.29. And if we can see the demonstrative there.

Dr. Kent, would that molar ratio change your opinion that Mylan's product is not inch fringing the co-polymer-1 limitation of the patents in suit?
A. No. This doesn't change the molar ratios. It just changes the way the numbers are represented. What in tells me is there are 5.98 alanines for every 1.29 tyrosines, 2.02 glutamic acids for every 1.29 tyrosines, and 4.70 lysines for every 1.2

tyrosines, the ratios are unchanged. In my opinion, it's unchanged.

Q. And what is the tyrosine molar fractions seen here reflect in terms of the tyrosine content of Mylan's product as compared to copolymer-1 composition of exactly 6:2:5:1?

A. What it tells me is that there's approximately 30 percent more tyrosine present in -- reflected in the numbers shown here, and these are for Mylan's product, I believe.

Q. Correct, Dr. Gokel's calculation, yes.

And Dr. Kent, can those numbers simply be rounded to 6:2:5:1 in your opinion

A. No, there's no justification for rounding. These are the actual numbers for the molar ratio.

Q. Now, do you have an opinion as to why the molar ratio of both Mylan's proposed product and Teva's Copaxone vary so significantly from approximately 6:2:5:1?

A. Yes, I do. It's, as we've seen in the number of the documents, that I've referred to earlier in my testimony, the batches of co-polymer-1 prepared with HBr and acetic acid may contain up to 30 percent bromotyrosine, and consequently they, the amount of tyrosine determined in those preparations will be unexpectedly or unusually low leading to a high molar ratio.

If you used phenol to pretreat the HBr and acetic acid used in the first deprotection step, then you get reflected in the final amino acid analysis the full tyrosine content of the

protected co-polymer-1, and the ratios for the other amino acids to tyrosine consequently are lowered.

Q. All right. Does Mylan use phenol in its manufacturing process?

A. It does.

Q. Now, have you prepared an exhibit showing the molar fractions and molar ratios for different co-polymer-1 compositions made using phenol?

A. I have.

Q. All right, can we see that, please? And could you just briefly explain what we see on this chart?

A. Well, down the left we see the four amino acids present in co-polymer-1, alanine, glutamic acid, lysine and tyrosine. These are co-polymer-1 compositions made using phenols. So the fifth amino acid, bromotyrosine, is absent, is not present.

Then what I've shown is three different compositions or co-polymer-1. The first column shows the '072 phenol patent, molar fractions for co-polymer-1.

The second shows the molar fractions in the Copaxone label. And the third shows the molar fractions in Mylan's proposed glatiramer acetate product.

And if you look across the amino acid by amino acid starting with alanine, you can see that the molar fractions were identical .427. For glutamic acid, they're identical for the first two preparations and closely similar at .144 and

Mylan's product. For lysine they're identical for the first two preparations and closely similar at .336 for Mylan's product.

And then if we look at the last line, the tyrosine mole fractions, you can see it's .095 for the first two preparations, and closely similar at .092 for Mylan's proposed product.

On the right I've shown the corresponding calculated molar ratios for these three preparations. And, once again, you can see that these are very closely similar for all four amino acids.

MR. ANSTAETT: All right, your Honor, I would move this slide into evidence under Federal Rule of Evidence 1006.

MS. HOLLAND: I mean that rule, your Honor, is reserved for voluminous data, I believe, and I think Dr. Kent has read into the record what there is to be.

THE COURT: I'm sorry, I can't hear you.

MS. HOLLAND: I'm sorry, your Honor. I think 1006 is reserved for complex voluminous data and I don't believe this fits under that rule.

THE COURT: All right. Well, to the extent it does reflect the doctor's testimony, it would be easier for. Me I'm going to admit it.

MR. ANSTAETT: Thank you, your Honor.

THE COURT: I'll use it as a demonstrative aid as I

review the testimony.

MS. HOLLAND: Yes, your Honor.

THE COURT: Okay.

Q. Dr. Kent, would a person of ordinary skill in the art reading the patents in suit in 1994 believe that a molar ratio of approximately 6:2:5:1 would encompass the molar ratio of the Mylan proposed glatiramer acetate product?

A. No, they would not.

Q. Would a person of ordinary skill in the art reading patents in suit in 1994, believe that a molar ratio of approximately 6:2:5:1 would encompass the molar ratio of Copaxone?

A. No, they would not.

Q. All right. Briefly, Doctor, I want to switch gears here and ask you just a few questions, few more questions, and I want to talk about the issue of best mode.

Doctor, did one of your expert reports consider whether Teva's patents in suit comply with the best mode requirement of U.S. patent laws?

A. I did express an opinion on that in one of my reports, yes.

Q. All right. And what was your conclusion?

A. My conclusion was that the '808 patent did not comply with the best mode requirement.

Q. All right. Does that go for all of the patents in suit?

A. It does.

Q. Dr. Kent, is the formation of bromotyrosine and copolymer-1

mentioned anywhere in the patents in suit?
A. The formation of bromotyrosine is not mentioned anywhere in the patents in suit.
Q. Is the pretreatment of the HBr acetic acid solution with phenol in order to avoid the formation of bromotyrosine and co-polymer-1, is that mentioned anywhere in the patents in suit?
A. The pretreatment of HBr acetic acid with phenol is not mentioned anywhere in the patents in suit.
Q. All right. Is in your opinion, was Mr. Konfino aware in 1991 of the bromotyrosine that could form as a result of making copolymer-1 according to the methods described in the patents in suit?
MS. HOLLAND: Your Honor, I don't believe that the witness is competent to form an opinion about what Mr. Konfino was aware of. We've already heard testimony from about what the documents say.
THE COURT: Yeah, I'll consider the documents.
MR. ANSTAETT: Okay. All right. Thank you, your Honor?
THE COURT: That's sustained.
Q. All right. Let me ask you this, Doctor. According to the documents you've reviewed, did Mr. Konfino report in 1991 that the use of phenol successfully reduced the bromotyrosine in copolymer-1 below Teva's specifications?

A. Yes. Mr. Konfino did report that the use of phenol to pretreat HBr acetic acid reduced the bromotyrosine content of co-polymer-1 below Teva's specifications.
Q. All right. And based on documents you've reviewed, how did Mr. Konfino regard the use of phenol for producing low bromotyrosine co-polymer-1?
A. I'm sorry, I lost my concentration. Please repeat.
MS. HOLLAND: I have an objection here, your Honor. It's the same objection about this witness is forming opinion about what Mr. Konfino thought about the use of --
THE COURT: All right, why don't you ask the question again.
Q. Sure. Let me do it this way. Can we see PTX 708T, please? And page number here in a second. If we could look at the page with the Bates number 324554, please. And let's look at section two.
In this document, Dr. Kent, did Mr. Konfino describe how he regarded the use of phenol for producing low bromotyrosine co-polymer-1?
A. Yes, he did describe how to use phenol to bring the amount of bromotyrosine within Teva's specification.
Q. And if could just ask you to read the sentence that starts, among the many?
A. "Among the many reagents tried for removing the free bromine previous treatment with HBr acetic acid with 1 percent

phenol for a few hours proved to be the most convenient."
Q. All right. And if we could look at the second page of this exhibit, please?
A. I'm sorry, I couldn't hear you.
Q. I'm sorry. If we could look at the second page of the exhibit, please. And when was this document dated?
A. Oh, this is Mr. Konfino's August 1991 report.
Q. All right. And have you seen any documents authorized by Mr. Konfino between August 1991 and end of 1991 when he retired from Teva indicating that he had changed his mind about the use of phenol being the most convenient method for producing low bromotyrosine co-polymer-1?
A. I did not see any such documents that indicated that Mr. Konfino had changed his mind about the use of phenol for pretreating HBr acetic acid in producing co-polymer-1 in the time period from here till the end of 1991.
MR. ANSTAETT: Thank you, your Honor. I have no further questions.
THE COURT: All right. Cross-examination.
MS. HOLLAND: Yes, your Honor, thank you.
CROSS EXAMINATION
BY MS. HOLLAND:
Q. Good afternoon, Dr. Kent.
A. Good afternoon.
Q. Elizabeth Holland. We met at your deposition?

A. I'm sorry having, I'm having trouble hearing you so my hearing --
Q. Sure.
A. Go ahead, please.
Q. Yes, I'm Elizabeth Holland we met at your deposition?
A. We did.
Q. During your direct testimony you provided an opinion about the meaning of approximately 6:2:5:1?
A. I did.
Q. Do you recall that? And you said that approximately 6:2:5:1 would include experimental uncertainty, right?
A. That's the batch variation and experimental uncertainty, yes.
Q. And the number you gave was plus or minus 10 percent, is that right?
A. For two standard deviations encompassing both batch-to-batch variability and experimental uncertainty, yes, that's correct.
Q. All right. So in your opinion if a copolymer-1 differed in any single amino acid by more than 10 percent from 6:2:5:1, it would be different than co-polymer-1, is that right?
A. If any single amino acid differed by more than plus or minus 10 percent, in 6:2:5:1, yes, I think that's essentially correct, that's my opinion.
Q. Now, when you were forming your opinions in this case about

what approximately 6:2:5:1 meant, you considered the inventor's publications, right?

A. In considering what 6:2:5:1 meant, I read the inventor's publications, but in terms of what the approximately 6:2:5:1 meant, I relied on my own extensive experience in amino acid analysis.

Q. Well, isn't it true, Dr. Kent, that in your view reviewing the molar ratios for co-polymer-1 disclosed in the inventor's publication would inform a person of ordinary skill in the art as to the range of ratios covered by the claim term approximately 6:2:5:1?

A. I read the inventor's publications, yes.

Q. Okay. And, in fact, you believed that reviewing the molar ratios in those publications would inform the person of ordinary skill as to the range of ratios covered by approximately 6:2:5:1; that's right, isn't it, Dr. Kent?

A. I get the impression that you're quoting from something so.

Q. Do you agree with that statement?

A. I've read those publications. And if you said the question one more time, I'll answer directly. I'm not quite clear on what you're getting at.

Q. I'm just asking you a direct question. Dr. Kent, in your view, would reviewing the molar ratios for copolymer-1 disclosed in the inventor's publications inform a person of ordinary skill in the art as to the range of ratios covered by

the claim term, approximately 6:2:5:1?
A. Then I would say it would be one of the factors, but not the only factor that would inform their opinion.
Q. Okay. Now, one of the publications that you reviewed in forming your opinion was the 1971 paper by Teitelbaum and the other inventors in this case, right?
A. I read that paper, yes.
Q. All right. Now, why don't you look at PTX-499 in your binder, and that's the cross-examination binder I handed you.
A. I'm sorry, what was the number?
Q. 499?
A. 499, thank you.
MS. HOLLAND: This is already in evidence, your Honor.
THE COURT: Thank you.
Q. And this is the 1971 Teitelbaum article you reviewed, correct?
A. Yes, European General Immunology 1971, Teitelbaum, et al., yeah.
Q. Okay. And you understand that this 1971 Teitelbaum paper is actually cited to in the specification of the patents in suit, in this case, right?
A. I believe that's correct.
Q. All right. Let's look at table one in the Teitelbaum paper. You can blow that up, thank you. You see table one is entitled composition of copolymer-1; do you see that?

A. I see that the table was entitled composition of co-polymer-1, yes.
Q. All right. And there are two batches of co-polymer-1 listed in the table, correct?
A. On the right-hand side, molar ratio of amino acid and copolymer batch one and batch two, yes.
Q. Okay. Those two batches of co-polymer-1, right?
A. Yes. The heading on the table says copolymer-1, so these should be batches of co-polymer-1. Absolutely.
Q. Okay. And you see that batch two has a molar ratio of 6.7:2.1:4.2:1.0; do you see that?
A. I do.
Q. And you agree that the authors defined these batches as co-polymer-1, right?
A. I'm sorry, could you repeat the question?
Q. You agree that the authors of this paper, Dr. Arnon, Sela Teitelbaum, they define these two batches as co-polymer-1?
A. That's what the table here says. I'm not sure the word defined is the way I would use it or say it.
Q. But you've testified before that they defined it as co-polymer-1, correct?
A. Are you referring to my deposition?
Q. Well, why don't we look at the deposition at 119, nine to 14.
A. 119.

Q. It should be in the front pocket of the binder?
A. I'm sorry?
Q. The deposition transcript should be in the front pocket of your binder?
A. Oh the front pocket, this one. Yes.
MR. ANSTAETT: Your Honor, before we look at it, can we have a chance to review the -- follow our procedure; could I have just a moment to get to the page?
MS. HOLLAND: Yeah, that's why I gave --
MR. ANSTAETT: Ms. Holland, could you give a page number again?
MS. HOLLAND: 119, nine to 14.
MR. ANSTAETT: Your Honor, I object. I don't know that I've heard his testimony impeached.
THE COURT: Overruled. Go ahead.
Q. Dr. Kent, at your deposition were you asked the following question and did you give the following answer: "Question: Do you understand those to be both batches of copolymer-1, referring to table one in Teitelbaum 1971? Answer: Composition of copolymer-1 is the title for the table, and these are batch one and batch two, so, yes, the authors essentially defined these as batches of co-polymer-1."
Did you give that testimony?
A. I did give that testimony at that time.
Q. Thank you.

A. Yes.
Q. All right. If you go to -- can we look at page 247 of the Teitelbaum 1971 reference?
A. Remind me, which is the Teitelbaum?
Q. Sure, let's go back to PTX-499.
A. Thank you.
Q. Look at the last paragraph on page 247. There's a sentence, the first sentence has a -- starts with a second batch in the middle of the page. Can you highlight that? Yeah. Couple more lines through the words of the first line. Thank you. That's it, thank you very much.

Do you see in the 1971 Teitelbaum paper that the authors themselves say that the two batches have the same amino acid composition?
A. Yes, I see that. Yes.
Q. All right. So let's go back to table one now. You see the molar ratio of alanine is reported as 6.7?
A. For batch two, yes, I see that.
Q. Okay. And the difference from exactly six, in the way you were determining these differences, is about 12 percent, correct?
A. It's -- yes, that is absolutely correct, yes.
Q. And if you look at the molar ratio for lysine, which is given as 4.2 difference from exactly five in the way that you've been determining these differences is about 16 percent,

right?
A. I'm sorry, from exactly five -- why did you say, exactly five?
Q. 6:2:5:1?
A. We're not talking about 6:2:5:1. We're talking about batch two. I'm sorry.
Q. I'm asking you, Doctor, in your opinion --
A. Oh, I thought you were comparing batch two and batch one from your first question.
Q. No, I'm sorry. Let's compare batch two to exactly 6:2:5:1?
A. Oh, okay. Sure.
Q. All right. And if you look at the molar ratio of lysine, you see it's 4.2?
A. Yes.
Q. And the difference from exactly five is about 16 percent, right. Is that correct?
A. Yes.
Q. So according to your definition of approximately 6:2:5:1, which would include up to 10 percent variations, batch two of copolymer-1 of the 1971 Teitelbaum paper, which is actually defined as co-polymer-1, would not be copolymer-1; is that right?
A. That's correct. As I said in my deposition, that's probably why they never mentioned it again.
Q. All right. So it's your belief that the authors never

mentioned batch two of Teitelbaum 1971 again, is that right?
A. I believe there may have been one paper in which they mentioned it. But in all the publications that I looked at, with perhaps that one exception, they referred to the molar ratio as shown for batch one in this paper.
Q. All right. At the time you formed your opinions in this case, though, you believed that batch two of Teitelbaum was not cited in any subsequent papers, right?
A. I, at the time I formed my opinion -- I'm not sure of the answer to that question. It would require me to recreate my state of mind back when I formed the opinion.
Q. Well, let me see if I can refresh your recollection. Why don't you the look at your deposition again, page 119?
A. Thank you.
Q. And you can look at lines -- line 24 on page 119 through line one on page 120?
A. Yes. From line 24 on 119 to?
Q. Line 1 on 120.
A. Yes. Ah, so at that time I said to the best of my knowledge at that time it was not cited in any of their subsequent papers.
Q. All right, I'd like you to take a look in your binder now to PTX-976?
A. PTX976.
Q. Yes. And do you see this is a paper by Ruth Arnon, one of

the inventors of the '808 patent, of the patents in suit?
A. Yes, I see this is authored by R. Arnon, who I take to be Ruth Arnon, yes.
Q. All right. And if you look at the previous page, this was published in 1975?
A. If you'll represent that the previous page is part of the publication. I don't see a date anywhere on the paper itself.
Q. Look at the first page at the bottom if you like to satisfy yourself that it says 1975?
A. I have no way of telling if that's part -- I mean, if you'll represent to me that it goes with this paper, I'll agree that it says 1975 on the front page.
Q. All right. I'd like to go to page 274 of this article. Do you see there is a section titled suppression of EAE with a synthetic material?
A. I do.
Q. All right. Then if you look at table 16.1 on page 275, you see that it refers to cop-1 batch two; do you see that?
A. Oh, I'm sorry, I was distracted by the ratios for batch one on the page you just directed me to.

Yes, it has two lines, one is cop-1 batch one and the other is cop-1 batch two.

Q. Okay. So this is a subsequent paper that refers to batch two from the 1971 Teitelbaum article?
A. I believe that I was referring to the amino acid ratios

when I made that statement.
Q. All right. So why don't we look at PTX-508 in your binder.
A. 508, yes.
Q. All right, sorry. I'll catch up. Are you on PTX-508?
A. I am.
Q. All right. And you see this is a European Journal of Immunology article from 1973?
A. I do.
Q. And if you look at the authors, you'll see that Teitelbaum, Arnon and Sela are authors on this paper?
A. I see Dvora Teitelbaum, Ruth Arnon, M. Sela along with Cynthia Web are also on this paper, yes.
Q. All right. Now, I'd like you to go to table one on page 280 of the article.
A. I see table one. It's headed "Composition of synthetic polypeptides."
Q. Right. And you would agree with me, would you not, Dr. Kent, that this article shows the amino acid compositions of both copolymer-1 batch one and copolymer-1 batch two?
A. Yes. They, the first two columns show the amino acid composition for co-polymer-1 batch one and copolymer-1 batch two, that's correct.
MS. HOLLAND: Plaintiffs move PTX-508 in evidence.
MR. ANSTAETT: No objection, your Honor.
THE COURT: Admitted.

(Plaintiff's Exhibit 508 received in evidence)

MS. HOLLAND: As well as PTX-976.

MR. ANSTAETT: Again, no objection.

THE COURT: Admitted.

(Plaintiff's Exhibit 976 received in evidence)

Q. Now, I want to actually go back to PTX-976 just for one minute.

A. PTX-976, is that correct?

Q. Yes.

A. Yeah.

Q. Now, you have said earlier that that paper didn't give you the amino acid molar ratios for batch two; do you recall saying that?

A. I'm sorry, could you repeat that?

Q. Yes. Dr. Kent, do you recall testifying --

A. You understand that I'm hard of hearing. I have hearing aids in both ears.

Q. I'm doing my best to keep my voice up.

A. Okay, great. Thank you. Please go on.

Q. All right, I'd like you to look at page 285, table 16.8?

A. 287?

Q. 285?

A. 285.

Q. In looking at table 16.8 -- can we blow that up, please? You see that this article also has the amino acid ratios for

both batch one and batch two from Teitelbaum 1971?
A. Yes, I see this table labeled 16:8, composition of co-polymer-1 lists both batch one and batch two amino acid compositions, yes.
Q. All right. Now, you would agree with me that in addition to looking at the authors' publications to determine the scope of approximately 6:2:5:1, the person of ordinary skill in the art would look at the prosecution history of the patents in suit in this case, right?
A. I doubt whether a person -- this is one of ordinary skill in the art as I defined it. So this is a research chemist working with copolymers of this type. I doubt whether they'd be looking at the prosecution histories.
Q. Okay. So I just want to make sure I understand your opinion. Is it your opinion that the prosecution history of the patents in suit in this case is not relevant to determining what approximately 6:2:5:1 means?
A. No, I wouldn't go that far either. That's not what you asked me. You asked whether one of normal skill would consider the prosecution histories, and I don't think they would.
Q. All right. But you actually did look at some of the prosecution history in this case, when you were forming your opinions, right?
A. To be honest, at this moment in time, I'm not sure whether I did or not.

Q. All right. Well, maybe I can refresh your recollection again. Why don't you look at your rebuttal report. You have an attachment that has your materials considered?
A. Rebuttal report, yes.
Q. Yes?
A. Which page?
Q. Attachment F?
A. Attachment F. Yes.
Q. If you go to page three, you'll see there is a reference -- I'll wait for you. Are you there?
A. On page three, yes, prosecution history excerpt. I stand corrected.
Q. Okay. So you did review page nine of a December 2nd, 2004 amendment from the prosecution history with '539 patent, correct?
A. Thank you for refreshing my memory, yes.
Q. Okay. Now, let's take a look at that amendment. Why don't we go to PTX-20, it's listed as 20A in your binder.
MS. HOLLAND: Just for the record, your Honor, PTX-20 is the full prosecution history. We took an excerpt.
THE COURT: Okay.
MS. HOLLAND: Which is the amendments referred to and just marked as 20A for convenience.
THE COURT: All right. Thank you.
MS. HOLLAND: I understand PTX20 is already in

evidence.

THE COURT: I believe it is.

MR. ANSTAETT: Your Honor, we have no objection to using 20A as an excerpt.

THE COURT: All right. Thank you.

Q. All right. So I'd like to go to page nine, which is the page you said you referred -- you reviewed in forming your opinions. If we blow up the third paragraph, please.

Now, do you understand that this amendment was Teva's representation to the patent office of what the term co-polymer-1 means in this case?

A. That's my understanding, yes.

Q. Okay. And you understand that somebody who wanted to understand what Teva thought co-polymer-1 means in the patent could go to the prosecution history and look it up right there, right?

MR. ANSTAETT: Your Honor, I'm going to object to these line of questions. This is -- he is not here as a lawyer. This is a one of the patents.

THE COURT: I know, I understand. Just keep moving.

MR. SKILTON: I just want to make sure he understood what he was reviewing when he reviewed it.

THE COURT: All right.

Q. So in the first sentence of this amendment, it's the first sentence of the third paragraph on page nine of the amendment,

Teva stated to the patent office "In addition, the term co-polymer-1 is not limited to the specific molar ratio of amino acids." Do you see that?
A. I do.
Q. And do you also see, if you go a couple of lines down, do you see -- maybe you can highlight -- the two amino acid ratios on the line above there -- do you see that Teva specifically points out to the patent examiner the amino acid ratios of both batch one and batch two from the 1971 Teitelbaum paper?
A. I'd like to take a moment to read the entire paragraph if I may.
THE COURT: Sure.
Q. Please, go ahead.
(Pause)
A. Yes, I've read the entire paragraph. Could you repeat the question, please?
Q. Yeah. My question was, do you see that Teva referred the patent office to the amino acid molar ratios of batch one and batch two from Teitelbaum 1971?
A. No, I do not see that. I see that they said that after amino acid hydrolysis, these were determined to contain glutamic acid, lysine, alanine, tyrosine, and a molar ratio of either 1.9, 4.7 to 6.0 to 1, or 2.1, to 4.2 to 6.7 to 1.
If you're asking me whether these match, these values match the values of co-polymer-1 batch one and co-polymer-1

batch two in the 1971 Teitelbaum paper, I would agree that they do.

Q. And actually if you look in the previous paragraph, there is a reference to that 1971 paper; do you see that?

A. Yes, you're quite correct.

Q. Okay. Then in the sentence you were reading it says in Teitelbaum; you see that?

A. I do see that.

Q. Okay. So now you understand it is a reference to 1971?

A. Yes, it's a direct reference. You're quite correct.

Q. All right. I'd like to now focus on the next part of the paragraph where it begins, in Bornstein, et al. And I'd like to focus in on the amino acid molar ratios that appear on the second-to-last sentence of that paragraph.

A. That sentence, which one are we talking about? The one starting however?

Q. There is sentence on the bottom that says "However, when these batches were retested using total amino acid analysis, a molar ratio of 1.9 to 4.0 to 6.0 to 1.0 or 1.8 to 3.9 to 5.7 to 1.0 or 1.9 to 4.0 to 6.3 to 1.0 respectively was obtained." Do you see that?

A. I do see that.

Q. Okay. And then what Teva says to the patent office is "Thus, co-polymer-1 does not refer to a specific molar ratio of amino acids." Do you see that?

A. I see written here it says, thus, copolymer-1 one does not refer to a specific molar ratio of amino acids.

Q. Okay. Now, I put together a slide with these three different amino acid molar ratios that appear in the prosecution history of the patents in suit in this case. So why don't we go to slide one.

Feel free to check the numbers. But what I did here was I put in the molar ratios for those three batches that are listed in the prosecution history?

A. There's one point I would like clarification on here. It --

Q. I'm sorry, Dr. Kent, I'm sorry, let me ask the questions, then if there's something you don't understand about one of my questions, we can deal with it then.

Right now I just ask you whether you agree that I put up on the slide the molar ratios set forth in the prosecution history

MR. ANSTAETT: Your Honor, I object to this line of questioning. This is not in any expert report that's been filed in this case. She's asking him to compare a bunch of things. When he's asking for clarification, she's cutting him off.

THE COURT: I'm going to let him ask for clarification or answer the question.

Go ahead, Dr. Kent.

A. Yes, those are the numbers. But in the sentence that you take the numbers from, it says that it retested using total amino acid analysis.

Q. Doctor, I'm sorry. For right now I just want you to answer my question. The only question on the table was, are those the numbers that -- are those the right numbers from the three molar ratios I just read from in the prosecution history?

MR. ANSTAETT: Your Honor, I think he's entitled to ask for some clarification on this.

THE COURT: You're going to have every opportunity to get up again.

MR. ANSTAETT: Thank you, your Honor.

THE COURT: Doctor, at the moment -- I mean, if you like I can sit here and compare the numbers.

Are those the same numbers?

MS. HOLLAND: I was hoping don't to have to do that, your Honor.

THE COURT: Are those the same numbers that were just referred to?

THE WITNESS: Those are the same numbers, yes.

THE COURT: Okay, next question.

Q. Thank you. So I want to look at the differences from exactly 6:2:5:1, according to the way you were calculating, all right, which is to look at each of the amino acids separately and to figure out the relative difference.

So why don't we -- can we have the next -- thank you. So you can feel free to check my math, but the difference from lysine between batch 320 with a molar ratio of 4.0 zero, the difference from exactly 6:2:5:1 is 20 percent, correct?

A. Using those numbers there, using the number for the same batch in the previous sentence, no.

Q. Now, let's go to batch 340. Can you put in the numbers, please? You agree with me there that the difference in lysine between 3.9 and five exactly the way you tell the Court it should be calculated, is 22 percent, correct?

A. Yes.

Q. All right. Then can we do the same for batch 400, please. And again here the difference in lysine from 4.0 in batch 400 to exactly 6:2:5:1 calculated the way you say it should be calculated, is 20 percent, right?

A. That's what it says on this table, yes.

Q. Okay. And according to your analysis in this case, these batches with these molar ratios would not be co-polymer-1, right?

A. I would need to understand the question I haven't had an answer to before I could answer that question.

Q. Would batches, with these molar ratios as shown on this slide, in your view, be co-polymer-1?

A. I need to know what total amino acid analysis means.

Q. You testified about amino acid analysis on your direct

examination, correct?
A. Yes, I did.
Q. Assuming these are molar ratios calculated in the way you just talked about calculating them in your direct examination, these three batches that Teva told the patent office explicitly were copolymer-1, would not be copolymer-1 under your definition, right?
A. The lysine differs by more than 10 percent, which I would regard as an indicator of difference from exactly 6:2:5:1.
Q. And these batches, in your view, would not be co-polymer-1?
A. In point of fact, my opinion was not about differing from exactly 6:2:5:1. It was about differing from 6:2:5:1 plus or minus 10 percent for each ratio.
Q. I'll ask you one more time. Would these batches be co-polymer-1, in your opinion?
A. I would have to do the calculations. But I believe that I would consider these to be different than copolymer-1 of approximately 6:2:5:1 .
Q. All right, we can take that down.

Okay, I want to change topics now and talk about how a person of ordinary skill would go about determining a molar ratio for a polypeptide sample.

So I think you testified in your direct that you would take -- the person with ordinary skill would take the sample, divide it up into the different amino acids, and then determine

the number of moles for each amino acid; is that right?
A. Essentially, yes.
Q. Okay. And once you have determined the number of moles, you could determine the molar fraction, right?
A. Yes, that's the way you do it. You determine the amount of each amino acid, then you determine the molar fractions for each amino acid, that's correct.
Q. Okay. And I think you referred to that molar fraction data in your direct examination as the primary data, right?
A. It's primary in the sense that it's the first thing you normally calculate from the experimental values for each amino acid.
Q. And as we saw in your direct, the numbers that Mylan reports for its product in its ANDA are molar fractions, right?
A. That's correct.
Q. Mylan does have molar ratios?
A. Mylan reports molar fractions in its ANDA.
Q. Okay. Now, in your view, it is correct, isn't it, that molar fractions are more useful to a scientist than molar ratios?
A. Yes, that is my view.
Q. Okay. And as a scientist, you would prefer to compare molar fractions versus molar ratios, right?
A. I've, I've never really thought of it in terms of a preference, so I'm not sure what you mean.

Q. All right. Why don't we you look at your deposition, page 132, line 25. Page 132, line 25 to 133, line four.

A. It's my reading of this is the -- you said that I would prefer, and I agreed with you.

MS. HOLLAND: Can I put it up on the screen, your Honor?

THE COURT: I think he just said he agreed with you. You can keep moving.

MR. SKILTON: Okay, thank you.

Q. And in your view, Dr. Kent, the best way to compare samples is by comparing their molar fractions rather than their molar ratios, right?

A. I think based on the documents I've read, that that is the way that the specifications are based, and so I guess that would be considered the best way.

Q. And if you wanted to determine whether a sample had a molar ratio of 6:2:5:1, you should really be doing the comparison at the mole fraction level, right?

A. Well, obviously as has been demonstrated in the testimony we've heard so far, not only my own, you can use both molar fractions and molar ratios.

(Continued on next page)

Q. So it would be completely appropriate in your view to compare molar fractions?
A. Between two batches of copolymer-1 to decide whether they're the same or different?
Q. Yes.
A. Yes, that would be one way of doing it.
Q. It wouldn't only be one way of doing it, Doctor; that in your view would be the best way of doing it, right?
A. I believe I already answered that question. I think from what I've seen in the specifications for copolymer-1s from various sources, that these are usually given as molar fractions, so I would assume that that is the best way of doing it.
Q. Now, in all the slides and all the molar ratio data that we saw from you today, we didn't see the molar fraction for 6:2:5:1, right? That wasn't in any of your slides.
A. To be honest, I'm not sure. I'd have to look back through at this point, but if you say so, sure.
Q. Right. And in fact, you never compared the molar fraction of Mylan's product to the molar fraction of 6:2:5:1, right?
A. Molar fraction of Mylan's product to the molar fraction of exactly 6:2:5:1?
Q. Yes.
A. I would need to look at the slides. But again, if you say so.

MR. ANSTAETT: Your Honor, I object because I believe it misstates the testimony. In his direct examination he gave the molar fraction for exactly 6:2:5:1, the tyrosine.

THE COURT: You can take it up on redirect. Go ahead, Ms. Holland.

MS. HOLLAND: Thank you, your Honor. Could we put up my slide 5, Mr. Chase? Thank you.

Q. So this is just looking at one batch of Mylan's drug substance. You agree that exactly 6:2:5:1 has the molar fractions that are shown in the first column here, right, .429 alanine, .143 glutamic acid, .357 lysine and .071 tyrosine?

A. Yes, I do.

Q. Okay. And Mylan's molar fraction data is exactly what you put up in your direct testimony, right?

A. I believe it is, yes. That's in the third column.

Q. So a sample that was exactly 6:2:5:1 would have 7.1 percent tyrosine in it, right?

A. I thought we were talking about molar fractions.

Q. Well, can't .071 be expressed as 7.1 percent?

A. Not if we're talking about molar fractions.

Q. Can .071 be expressed as 7.1 percent?

THE COURT: I think he's answered that.

A. Molar fractions by definition add up to one.

Q. Now, Dr. Kent, you would agree that the difference in terms of total percentage of tyrosine in a batch of Mylan's product

versus exactly 6:2:5:1 would be the difference between .092 and .071, right?

A. The difference between exactly 6:2:5:1 molar fraction for tyrosine of .071 and Mylan's molar fraction of .092 would be .021.

Q. And that would be about 2 percent, right?

A. No, it would be about a 30 percent difference in the tyrosine content.

Q. If you look at -- I'm asking you about the percentage of tyrosine in the mixture. The percentage of tyrosine in the mixture, in Mylan's product is about 9.2 percent, isn't that right?

A. I thought we were talking about molar fractions.

Q. I'd like to talk about percentages for a minute if you don't mind?

A. Would you start from the beginning and let's do it as percents, please.

Q. Dr. Kent, I'm just asking you one question, now. If you look at Mylan's molar fraction, that gives you the fraction of each of these four amino acids in the mixture as a whole, right?

A. It does.

Q. And the tyrosine is .092, right?

A. That's correct.

Q. And the tyrosine in the mixture as a whole for exactly

6:2:5:1 would be .071?
A. The molar fraction of tyrosine in exactly 6:2:5:1 is .071.
Q. Okay. You can take that down. All right. Now, you testified in your direct examination -- I wrote it down to be sure I got it right -- I'm sorry, let me start over again. You testified on direct examination that you converted the molar fractions of Mylan's product by dividing it by the molar fraction of the least abundant amino acid, right?
A. Yes. The conventional way of calculating molar ratios is to take the molar fractions and divide through by the molar fraction of the least abundant amino acid.
Q. But in your personal experience working with polypeptides, you did not typically normalize to the least abundant species, right?
A. Could you repeat the question?
Q. Yes. In your personal experience working with polypeptides, you did not typically normalize to the least abundant species, right?
A. I think we established in my deposition that I had never had any direct experience in doing the amino acid analysis of a copolymer of this type.
Q. We did establish that. In the copolymer-1s that you worked with, you did not typically normalize to the least abundant species, right?
A. I didn't work with copolymer-1.

Q. My question is a little different. In the polypeptides that you worked with --
A. Yes.
Q. You did not typically normalize to the least abundant species, right?
A. These were homogenous polypeptides of a single peptide sequence and therefore would be expected to have integral numbers of each amino acid, and when I was making polypeptides I knew what that integral number was expected to be, so when I got the amino acid analysis, I would adjust the molar ratios to bring those numbers as close as possible to the expected number and then look at the outliers.
Q. I think that means the answer to my question is correct, you did not normalize to the least abundant species.
A. There's absolutely no reason to normalize for that type of analysis, no. You're quite correct, yes.
Q. You testified on direct that you performed hundreds of amino acid analyses, correct?
A. That's correct.
Q. But those were not for materials like copolymer-1, correct?
A. I have had no experience, no direct experimental experience with a copolymer-1 like composition.
Q. Now, the patent doesn't explicitly state that molar ratios should be normalized to tyrosine, right?
A. I'm sorry, I didn't catch the first part.

Q. Let me focus you, in the patents in suit in this case --
A. Yes?
Q. There's nowhere in the patents that says that the molar ratios should be normalized to tyrosine, right?
A. I don't believe that it says normalized to tyrosine anywhere in the patents in suit.
Q. And you are aware that Professors Arnon and the other inventors on the patents didn't always normalize to the least abundant amino acid when they reported molar ratios, right?
A. I had the impression from most of the publications of theirs that I looked at that they reported tyrosine as 1.0 in their molar ratios.
Q. My question was a little different, Doctor. Professor Arnon and the other inventors here generally when they reported amino acid molar ratios in their publications, they did not always normalize to the least abundant species?
A. I think I answered that question. My impression from what I've read of their publications is that they usually reported the tyrosine as 1.0.
Q. All right, let's go back to your deposition, then, page 118, line 20. Lines 20 to 25 on page 118.
MR. ANSTAETT: Your Honor, I object to this.
THE COURT: Ask your question again.
MS. HOLLAND: Yes, your Honor.
Q. Professor Arnon and the other inventors in this case did

not always normalize to the least abundant amino acid when they provided molar ratios, correct?

A. And my answer is the same. In most of the publications that I read they report the value of tyrosine as 1.0, which implies that they have done the ratios of the other amino acids to that, to tyrosine and that is what we call colloquially normalization.

MS. HOLLAND: Your Honor, I believe there's an inconsistent statement in the deposition.

THE COURT: I don't. If you want to ask a very specific question --

MS. HOLLAND: I think I asked exactly what was in the deposition.

THE COURT: I must have been on a different part of it. I thought you were referring to 118 line 20.

THE WITNESS: She did.

THE COURT: Did I get the wrong page and line?

MS. HOLLAND: That's correct, your Honor. I believe I asked the witness exactly what his answer was at pages 24 to 25.

THE COURT: No, the question you put wasn't exactly the same. That's all I'm saying. I don't -- you know, this is not -- ask it exactly as you asked it in the deposition and we'll see what happens.

Q. Is it correct from the '550 patent and from the 971

Teitelbaum paper that Drs. Sela, Arnon and Teitelbaum didn't always normalize to the least abundant amino acid?

A. I have no idea. Can we look at that, please?

Q. Yes, sure. Why don't we look at DTX 1219. Are you there, Dr. Kent? And I'd like to focus in on column 2, line 30. Do you see that there's a molar ratio there of 1.5 to 5 to 3.5?

A. I'm sorry, which molar ratio am I looking at? Oh, the one that's highlighted. 1 to 1--

MS. HOLLAND: The bottom one? Yes, thank you.

A. Oh, the one underneath. Yes, I do see that.

Q. And you agree that that molar ratio of 1.5 to .5 to 3.5 is not normalized in the least abundant species?

A. I think we need to look at the whole sentence here. If I have -- it says that similar results were obtained with a soluble copolymer comprising tyrosine, aspartic acid, alanine and lysine in a molar ratio of 1:1.5:5:3.5 and with another such copolymer comprising glutamic acid, alanine and lysine in a molar ratio of about 1.5 to 5 to 3.5. I think they made an exception here in order to compare the last three amino acids in a copolymer that does not contain the first amino acid.

Q. And the exception being that they didn't normalize to the least abundant species?

A. That's quite correct, yes.

MS. HOLLAND: Your Honor, would this be a good time to break?

THE COURT: How much longer? Just approximately. I'm not going to hold you to it.

MS. HOLLAND: I would say less than an hour.

THE COURT: All right, we'll take a ten-minute break.

(Recess)

THE COURT: All right, Ms. Holland.

MS. HOLLAND: Thank you, your Honor. I'd like to put up the head slide, please. Thank you.

Q. Dr. Kent, this is a slide you used in your direct examination, right?

A. Yes, that's correct.

Q. And what you have, you have three columns showing molar fractions and then three columns showing molar ratios. Right?

A. Yes, that's correct.

Q. Now, I'd like to focus in first on the row that says "lysine" on it. Do you see that?

A. I'm sorry, I didn't hear that.

Q. I'd like to focus in on the row that says "lysine".

A. Yes.

Q. So you say '072 phenol patent molar fraction for copolymer-1 the lysine is .338?

A. That's what it says in the table, yes.

Q. For the fraction in Copaxone label it says .338, right?

A. That's what it says on this table yes.

Q. And the fraction in Mylan's product it says .336, right?

A. That's right.
Q. So when you look at the molar fractions, the Mylan product has a lower lysine molar fraction than the other two lots.
A. 1.002 well within the experimental uncertainty.
Q. If you look at the molar ratios for lysine you'll see that the molar ratio of lysine in Mylan's product is actually higher than in the '072 patent of Copaxone products, right?
A. That's right.
Q. So when you switch from molar fraction to molar ratio the relative difference in lysine among the three lots flip.
A. Molar ratios are always compared to another amino acid. Here the tyrosine is reported as 1.0, so it's a ratio of .336 to .092. Which is 3.7, which is reported in the lysine in the third column.
Q. All right, let's change topics. I want to talk about the bromotyrosine impurity you testified about in your direct examination. I think we saw in that animation that that bromotyrosine impurity is performed during the debenzylation step?
A. Yes, the first deprotection step with HBr acetic, yes.
Q. And what happens if the HBr contains free bromine some of the tyrosine can become brominated, right?
A. Yes, if there's a bromine impurity in the HBr that's been used then you get bromotyrosine, yes.
Q. That means that the bromines that are swimming around can

attach themselves to tyrosine, is that right?
A. While they react to the plus species, that's correct.
Q. If you had HBr that was very pure and didn't contain any free bromine, then you wouldn't have bromotyrosine formation, right?
A. That's correct.
Q. So one way of controlling the formation of bromotyrosine would be to use high quality HBr that didn't have free bromine, right?
A. Yes, that's absolutely correct.
Q. Okay. Now, in your opinion was the use of high quality HBr one way that Mr. Konfino found to control the level of the bromotyrosine impurity?
A. I never saw anything in Mr. Konfino's lab notebooks that I remarked on that said anything about the purity of the HBr, except for the one exhibit that I showed where he deliberately added bromine.
Q. So in your opinion, the source of the HBr that Mr. Konfino used would not be considered his best mode?
A. I'm sorry would not be?
Q. Considered his best mode.
A. His best -- I'm not catching --
Q. His best mode.
A. Oh, his best mode. So the question as I understand it is would I consider the source of the HBr acetic as a best mode,

is that correct?
Q. That's the question.
A. It would be unusual to see that in the patent specifying a source.
Q. So you wouldn't consider that to be a best mode?
A. Well, best mode as I understand it is the inventor is supposed to describe their best way of doing the invention at the time the patent is filed and if there was a reagent from a particular source, then yes, they'd be obligated to put it in as part of their best mode.
Q. So was the source, I'm asking you a specific question. Was the source of Mr. Konfino's HBr --
A. Yes.
Q. In your view, was that Mr. Konfino's best mode?
A. I don't understand the question. I'm sorry.
Q. All right. As you testified, one way of minimizing the bromotyrosine impurity would be to use high quality HBr, right?
A. HBr acetic acid you knew to contain no bromine, yes.
Q. And that would be a perfectly good way of controlling bromotyrosine, correct?
A. That would be one way of controlling the bromotyrosine formation yes.
Q. And another way would be the use of phenol, is that right?
A. Another way of insuring that there's no bromine in the HBr acetic acid is to treat with a scavenger such as phenol.

Q. And a person of ordinary skill in 1994 would know that phenol was a bromine scavenger?
A. In the context of bromotyrosine formation in copolymer-1 or another context?
Q. I'm asking you in general. Was it known generally in the art that phenol could be used as a bromine scavenger?
A. A person of ordinary skill in the art in 1994 would know that phenol would react with bromine.
Q. Now, I want to put back up your slide Kent 4. That's going to go up on the screen in a second. It says effective phenol on cop-1 molar ratio. That was the title. Thank you.

So what I understand you saying here is that if you use HBr acetic acid containing free bromine, you're going to get a molar ratio of approximately 6:2:5:1?
A. Starting from the protected copolymer-1, if you have bromine as an impurity in the HBr acetic acid step for the -- I should specify that the protected copolymer-1 has to be as made in the '808 patent, then, yes, you'll get approximately a 6:2:5:1 molar ratio.
Q. And in your view that's because the copolymer-1 would contain a bromotyrosine impurity, right?
A. My view is that a large significant fraction of the tyrosines in the product fully deprotected copolymer-1 will have been converted to bromotyrosine.
Q. So in your opinion, in order for a sample to be copolymer-1

within the meaning of the patent, it would have to have a bromotyrosine impurity, right?
A. I don't think that I can -- say the question again, just so I can focus on the exact wording.
Q. Just let me make sure I understand your opinion. You're saying in order to get the molar ratio of approximately 6:2:5:1, you need to have a bromotyrosine impurity, right?
A. If you used the exact procedure shown in example 4 of the '808 patent, which is what we're talking about, then the way you get 6:2:5:1 is by having bromotyrosine formed.
Q. So in your opinion, pure copolymer-1 that didn't have a bromotyrosine impurity would not be copolymer-1 within the meaning of the patent, right?
A. I'm offering my opinion for example 4 and in example 4 in order to get 6:2:5:1 you'll have to have bromine in the HBr acetic acid. Speaking generally, there are other ways of getting a copolymer of this type with that amino acid ratio, but not using the procedures shown in example 4.
Q. Now, I want to ask you about the bottom arrow. You say the way to get to that molar ratio that you have there 4:5:1:5:3:6:1 is to use HBr acetic acid with phenol, right?
A. That's correct.
Q. But as we just discussed, there's another way to do that, right, which is to use high quality HBr acetic acid?
A. If you can be sure that your HBr acetic acid does not

contain bromine and you take the protected copolymer-1 in example 4 from the '808 patent then you will get the ratio shown on the bottom without phenol, that's correct.

Q. So if a person of ordinary skill in the art performed the exact procedure for making copolymer-1 set forth in the '808 patent, and used high quality HBr without any free bromine in it, in your opinion would that product be copolymer-1?

A. I think that calls for a legal conclusion. I can tell you about the ratios and so on. I don't know about --

Q. In your view, if somebody of ordinary skill in the art followed the exact procedure for making copolymer-1 described in the patents and used high quality HBr acetic acid with no free bromine in it, would they come out with a product that was approximately 6:2:5:1?

A. I think that's slightly different than the question you just asked. If you used HBr acetic with no bromine in it and carried out the first deprotection step on the protected copolymer-1 as described in the '808 patent, then you'll get the molar ratio shown on the bottom line which I think is significantly different, which in my opinion significantly different from 6:2:5:1.

As I understand the Court's definition of copolymer-1 includes approximately 6:2:5:1, then I would not consider that to be copolymer-1.

Q. I just want to spend one minute looking at what this

bromotyrosine impurity is. Could we look at my slide 6, please? All right. Dr. Kent, you agree that on the left what you have is tyrosine, right?
A. That's a representation of the amino acid tyrosine, yes.
Q. And on the right is a representation of bromotyrosine, correct?
A. That's a bromotyrosine. I'm not sure if it's the correct one.
Q. Are you talking about the position of the bromine?
A. Indeed.
Q. Were you here this morning when Dr. Owens put up a slide that showed the bromotyrosine with the bromine in the position as shown on this slide?
A. That could be. I wasn't paying attention.
Q. Okay. In any event, bromotyrosine is the tyrosine molecule exactly the same except one position on the molecule has a bromine added, correct?
A. It is exactly the same. If you take the compound on the left and replace one proton with a bromine on the aromatic rim, then you have bromotyrosine, that's correct.
Q. So what happens in the debenzylation step is that you have the protected copolymer-1 chain that has glutamic acid, alanine, lysine and tyrosine, and that protected copolymer-1 chain stays the same whether or not you use phenol, but if you don't use phenol you're going to have some of these little

bromine additives attaching on to the tyrosine, right?
A. That's not correct. The bromine atom is not little. It's almost the same size as the aromatic rim shown here. These are all different chemical compounds. All amino acids share common structures. What gives them the different properties is the atoms that change.
Q. But you would agree with me that whether or not you use phenol you're going to have the same number of tyrosines in the chain, but if you don't use phenol some of the tyrosines in the chain will be brominated?
A. Some of the tyrosines will be in a different amino acid that we call bromotyrosine and you'll remember in my direct when I spoke about the confusion that the English language causes on this point.
MS. HOLLAND: I'm sorry, your Honor, I'm trying to move on.
Q. Now, I wanted to talk about your opinions about Mr. Konfino's work. You reviewed Mr. Konfino's deposition transcript, right?
A. I did.
Q. And you understand that Mr. Konfino testified that phenol was not part of his process, right?
A. Could you -- you said that it was not the part of his process.
Q. Yes.

A. I'm not sure that that was my interpretation of what I heard Mr. Konfino say in his deposition. I believe he said that it was not used in the Teva manufacturing process.

THE COURT: Ms. Holland, I'm going to get designations, right, from this deposition?

MS. HOLLAND: Yes. I was going to put it up, your Honor, but --

THE COURT: I don't know that it helps to have your interpretation and his interpretation.

MS. HOLLAND: I wasn't going to put the interpretation, your Honor. I wanted to show the actual testimony because I think there may have been some testimony this morning that wasn't exactly accurate in terms of characterizing the deposition. If you prefer to just look at it in chambers, your Honor, we'll do that.

THE COURT: I think you'll argue and I'll look at the deposition. I don't think this is productive.

MS. HOLLAND: Okay, your Honor.

THE COURT: Thank you.

Q. Let's talk about your testimony about Mr. Konfino's lab records, then. You agree that Mr. Konfino did not always use phenol in his experiments to make TFA copolymer-1, right?

A. Yes.

Q. And in some of his experiments he was able to obtain low bromotyrosine copolymer-1 without pretreating the HBr with

phenol, right?
A. Yes, that is absolutely correct.
Q. Now, in fact, up until the time he left Teva in 1991, he continued to make TFA copolymer-1 without pretreating the HBr with phenol, right?
A. Yes. I showed an experiment to that effect, one of the last entries in the lab books that were available to me, that's correct.
Q. You showed one example of that in your direct testimony. I would like to look at some others.
A. Oh, yes, there are others. That's absolutely true.
Q. So maybe we can cut this short. You would agree with me, Dr. Kent, that there were several experiments in the months leading up to Mr. Konfino leaving Teva where he made TFA copolymer-1 with low bromotyrosine content without using phenol?
A. I would need to refresh my recollection on the low bromotyrosine. I remember at least one example of that and there were several experiments in which he made TFA copolymer-1 from protected copolymer-1 using HBr acetic acid and without phenol along with a greater number of experiments where he did use phenol.
Q. Maybe we can quickly look at his lab notebook what it actually looked like, the last lab notebook that you saw before he left Teva. So why don't we go to PTX 52T. Page TEV, the

last three digits are 220. 1177220.
A. 220. Yes, I have that page.
Q. Okay, and you see this is a December 1990 experiment, is that right?
A. I do.
Q. And Mr. Konfino is making TFA cop-1?
A. Yes, from protected copolymer-1.
Q. And he does not add phenol to the HBr acetic acid, right?
A. There's no mention of phenol in my records and skimming of this, that's correct.
Q. And the bromotyrosine content is less than .5 percent, is that correct?
A. That's quite correct, yes.
Q. Then if we move on to the page that's 226. Again, Mr. Konfino is making TFA copolymer-1, is that right?
A. Mr. Konfino is making TFA copolymer-1 from protected copolymer-1, that's correct.
Q. And there is no phenol added to the HBr acetic acid, correct?
A. I see no mention of phenol on this page.
Q. All right, and the bromotyrosine content is again less than .5 percent, right?
A. That's on 227, and the bromotyrosine content is reported as less than .5 percent.
Q. So now let's go to another experiment on page 352.

A. I'm sorry was that 252 or 352?
Q. 352.
A. 352. Thank you. Yes.
Q. So this is another experiment where Mr. Konfino is making TFA cop-1 from protected cop-1 with HBr acetic acid that had not been pretreated with phenol, right?
A. There's no mention of phenol in this page so that's correct, yes.
Q. And then if you go to the next page 353 on the bottom, do you agree that the bromotyrosine content, again, less than .5 percent?
A. Yes, indeed. It's less than .5 percent, so I guess the HBr acetic had no bromine in it.
Q. Okay, now, page 354, that was one of the experiments you pointed to this morning, right?
A. I would have to double check that, but if you represent that, yes, I'll agree.
Q. Okay, and do you see there that Mr. Konfino is using HBr from Merck batch 391?
A. 390/1, yes, I see that.
Q. In that experiment no phenol is added, right?
A. There's no mention of phenol in this page.
Q. And the bromotyrosine is less than .5 percent if you go to the next page?
A. Yes, it's less than .5 percent.

Q. Now if you look at the next experiment in the lab notebook page 356.
A. Yes.
Q. Do you see Mr. Konfino is again making TFA cop-1 with the Merck 390/1 HBr, do you see that?
A. I do.
Q. And at this time there is phenol added?
A. He did.
Q. And do you see on the next page the result is exactly the same, whether or not he used phenol, less than .5 percent?
A. He says it's less than .5 percent. You can't tell if it's exactly the same. That appears to be his detection.
Q. So with that batch made with that Merck HBr Mr. Konfino got the lowest detection level whether or not he used phenol?
A. He has a bromotyrosine of less than .5 percent whether or not he used phenol, that's quite correct.
Q. And you agree that Mr. Konfino actually found more than one way to lower the bromotyrosine content, right?
A. Yes, he explored different ways of achieving reliably low bromotyrosine content, that's correct.
Q. And there are ways that worked in addition to phenol, right?
A. I believe there were, yes.
Q. Now, let me go back to a document you testified about on direct, DTX 999A, and you looked at manufacturing procedure

contained in that document, I think it was on page 365RC? This is a manufacturing procedure, right?
A. This is Teva Pharmaceutical Industries Ltd. manufacturing procedure cop-1 for injection in December 1989.
Q. Okay, and Mr. Konfino's name doesn't appear anywhere on this document, right?
A. I would have to check the document, but to the best of my recollection that's correct.
Q. And Mr. Konfino didn't actually work in manufacturing, did he?
A. Mr. Konfino was a process development chemist to the best of my understanding.
Q. That means he did not work in manufacturing, he worked at a bench, right?
A. In reading his deposition, I got the impression that there were times when he did work with the manufacturing people. So I don't know whether or not he worked in manufacturing.
Q. All right, I want to look at another document you were showed earlier, DTX 1270. This is a January 1993 document, right?
A. Yes, this is the annual review published internally in January 1993, looking at the lots from 1991 through 1992, that's correct.
Q. And again just to be clear, Mr. Konfino is not named as an author on this document, right?

A. No, it appears to be authored by Drs. Leonov and Gad.

Q. And it's actually dated two years after Mr. Konfino retired from Teva?

A. No, it's dated twelve or thirteen months after he retired from Teva. Retired at the end of 1991. This is January 1993.

(Continued next page)

Q. All right, and the page you pointed out in your direct testimony was 312175, it's numbered five on top. Do you recall testifying about this on your direct testimony?
A. I do.
Q. First line said cop-1 has been manufactured in a specially designed unit at Plantex; do you see that?
A. I do.
Q. You don't know what Plantex is, do you?
A. I have no direct knowledge of what Plantex is. Since one of the documents came as part of the discovery from Teva, I see somehow affiliated with Teva.
Q. You don't know whether Confino worked for the Plantex division, do you?
A. I have no knowledge of whether Mr. Konfino had anything to do with Plantex.
Q. And you also cited a section of the NDA in your direct testimony, DTX-1023; do you recall that?
A. Perhaps when I see it. Yes.
Q. Okay. And the NDA was filed years after Mr. Konfino retired from Teva, right?
A. It was filed -- my understanding is it was filed in 1995, and Mr. Konfino retired from Teva at the end of 1991, so, yes that's correct.
Q. All right. You also discussed the '072 patent on your direct examination, DTX-1925. The inventor on this patent is

not Mr. Konfino, right?
A. No. The inventor is Ben Zion Dolitzky.
Q. Do you know who that is?
A. I beg your pardon?
Q. Do you know who Mr. Dolitzky?
A. I have no idea who Mr. Dolitzky. The inventor know on this patent. I'm sorry?
Q. Did you try to find out who Mr. Dolitzky was?
A. No, I didn't. I read this patent on which he's listed and named as the inventor.
Q. Okay. Now this patent refers to a manufacturing process, right, I think you pointed had that out in your direct testimony.
A. The invention is, I would need the exact wording in front of me, but the invention is an unproven process.
Q. So, let's put it up in front of you then. Let's go to column two of the patent, line 16?
A. Yeah, some tension provides an improved manufacturing process, yes.
Q. And you just testified that you don't know one way or the other whether Mr. Konfino even worked in manufacturing?
A. Could you repeat that, please?
Q. Yes. You don't know whether one way or the other whether Mr. Konfino even worked in the manufacturing department?
A. I do not know one way or the other whether Mr. Konfino

worked in the manufacturing process, that's quite correct.
Q. Okay, let's go to PTX708T. This is another exhibit you testified about on direct, right?
A. Yes. This is Mr. Konfino's August 1991 report.
Q. All right, and let's go to page 324554. You testified about that page several times on your direct. And I'd like to look at the 2nd, I'm sorry, in the second section, the second paragraph?
A. Second paragraph.
Q. Yes. It's highlighted up on the screen?
A. Yes.
Q. Can you see that?
A. I've got it.
Q. And you pointed to the sentence where it says phenol was most convenient, right?
A. Yes, yes. Yes, Mr. Konfino.
Q. Okay. You don't know in what sense phenol was most convenient, right?
A. I have no direct knowledge of Mr. Konfino's state of mind, but I take from the patent of experimentation reported in his lab book that he found that the most reliable way of avoiding bromine in the HBr acetic convenient way was to pretreat with phenol.
Q. Okay. But you don't know whether when he said most convenient, he meant it was the least expensive way to do it,

right?
A. There are a variety of English language meanings to the word convenient, but I think in the context of looking through the patent of experimentation in his lab book, I would conclude, personally, that he thought that that, you know, if you wanted to be sure that it was done, this was the easiest way of making sure of that. And that's my sense of word convenient in this context.
Q. But you also know that phenol was something that was readily available at any peptide lab; is that right?
A. Absolutely. Phenol was widely used in peptide chemistry at that period.
Q. All right. And in that sense it was a convenient reagent to use?
A. It could well have been the nearest model when he put his hand out to the lab bench, yes.
Q. All right. Let's turn back to bromotyrosine for just a minute and then I'll be concluding.
You agree that bromotyrosine is an impurity in copolymer-1, right?
A. Bromotyrosine, if formed, according to what we've heard, is found throughout the polypeptide chains in the copolymer-1 composition, yes, that's correct.
Q. Okay. But it's defined in Mylan's ANDA as an impurity, right; you saw that this morning?

A. Yes. But I'm not sure that I understand the ANDA definition of impurity -- I mean the FDA's definition of impurity. I know what I understand by it.
Q. And bromotyrosine you understand is not the only impurity in copolymer-1?
A. I imagine there are a variety of low molecular weight impurities, some of which I think we saw this morning.
Q. Right.
A. And probably other impurities in the unpurified copolymer-1.
Q. And you understand, for example, that in the process for making copolymer-1, the lysine is protected with TFA, right?
A. Yes, that's correct. There's a trifluoracetyl group on the side chains of lysine.
Q. Right. So there might be, for example, some lysine with TFAs still attached to it in the final product?
A. Yes. I believe that they tested for fluorine in the final product.
Q. And the glutamic acid is presented with a gamma benzyl group, right?
A. That's correct.
Q. Right. And so there might be some glutamic acid with gamma benzyl still attached to it in the final product, right?
A. There might be, but -- yes, there could be small amounts of that sure.

Q. And there are other impurities, right?
A. Yes, absolutely.
Q. And minimizing impurities is a regular part of what's done at a pharmaceutical company when a product is being scaled up for manufacture, right?
A. Once again, I missed the first few words. Sorry.
Q. Okay. Minimizing impurities --
A. Yes.
Q. -- is a regular part of what is done when a product is being scaled up for manufacture?
A. Yes. Yes. The idea is to have a reproducable method of manufacture with a defined impurity profile, and those impurities should be below the limits set by negotiation with the FDA.
Q. Now, Dr. Kent, you have no reason to believe that bromotyrosine is toxic in any way, right?
A. I believe that I've seen a paper, although I couldn't cite the exact reference, where there were rat studies carried out in very high levels of bromotyrosine copolymer-1 showed toxicity.
Q. Well, let me -- is this something you recently read, Doctor?
A. I'm sorry?
Q. Is this something you recently read?
A. Is that something that I've recently read?

Q. Yes.
A. Yes, it is something that I've recently read.
Q. All right. Are you, you are aware that Teva found that bromotyrosine was nontoxic right; you saw that this morning?
A. Bromotyrosine copolymer-1?
Q. Yes.
A. Or bromotyrosine?
Q. You testified this morning that Teva found that bromotyrosine copolymer-1 was proven nontoxic, right?
A. I think what I said this morning is that the sentence in Mr. Konfino's report was unclear, but that if he meant bromotyrosine copolymer-1, then he was saying that Teva had found it to be nontoxic, that's correct.
Q. All right. You're not offering an opinion that copolymer-1 made using HBr acetic acid that had been pretreated with phenol is any less toxic than copolymer-1 sample that had not been pretreated with phenol, right?
A. That's outside my expertise. I'm not offering such an opinion. I'm responding to your questions.
Q. And you have no opinion on whether bromotyrosine and copolymer-1 has any affect on any biological property, right?
A. In the legal sense of opinion, no, I have no such opinion.
Q. That's outside of your area of expertise?
A. That's outside my area of expertise.
MS. HOLLAND: Thank you.

THE COURT: Redirect?

MR. ANSTAETT: Just a little bit your, Honor, please.

THE COURT: Sure.

REDIRECT EXAMINATION

BY MR. ANSTAETT:

Q. Dr. Kent, Ms. Holland showed you an exhibit, it was a slide, had a representation of a tyrosine and bromotyrosine; do you recall that?

A. I do.

Q. Nick, could we see the --let's go back -- keep going. There we go, that's good.

Dr. Kent, what we are we looking at here, please?

A. This actually shows in the upper panel a representation of a one particular sequence out of a random copolymer consisting of the alanine glutamic acid, lysine, tyrosine and bromotyrosine. On the bottom panel I've shown space filling representations of the tyrosine side chain that's on the left. This is the standard color used for oxygen. So this is the hydroxyl group, the tyrosine side chain, and on the right I've shown two bromotyrosine side chain, and as you can see the bromine atom is gigantic.

Q. All right. We can take that down.

Doctor, I want to look at PTX-52. We'll do a private screen because these -- I'm going to ask us to look, Nick, if we can get the last page please of PTX-52T, and let's go back a

couple pages to the last page that Mr. Konfino has any writing on. That's good. Actually, back one more so we can see the date.

Do you have that on your screen Dr. Kent?

A. I'm sorry, what was the question?

Q. Do you have that on your screen up there?

A. I do.

Q. All right. And what is the date of that experiment?

A. March the 21st, 1991. It's a page from Mr. Konfino's lab notebook.

Q. And this is the last lab book we looked at chronologically. You recall -- Nick, could we see PTX-708T, please?

And what was the date on this document, Dr. Kent?

A. I'm sorry?

Q. What was the date on this document, please, Dr. Kent?

A. The date on this document is August 1991.

Q. And was this the document in which Mr. Konfino reported that the most convenient method of ridding bromotyrosine from copolymer-1 was the use of phenol?

A. It is.

Q. Can we see slide five from Ms. Holland's -- maybe it is the -- oh this is the right one. I apologize.

Ms. Holland asked you, I believe if molar fractions were one of the primary ways of comparing data about amino acid ratios, is that correct?

A. Yes. You get the amino acid amounts, and one of the first steps is usually to convert them for this type of copolymer analysis to convert them to molar fractions.
Q. All right. And what is the -- what is the molar fraction for tyrosine in a copolymer-1 composition of exactly 6:2:5:1?
A. As shown here is .071.
Q. And what is the molar fraction for tyrosine for Mylan's product?
A. It is as shown on here is .092.
Q. And what's the relative difference in terms of tyrosine reflected by those molar fractions?
A. Mylan's product contains -- taking the data from this table, .022 molar fraction more tyrosine composition of exactly 6:2:5:1. And doing the math in my head, I think that's about 30 percent.
Q. All right, thank you. Ms. Holland also asked you about PTX-20A, and I wonder if we can see that. That's PTX-20. Do we -- can I ask some indulgence here maybe use the excerpt that Ms. Holland used?
And this was a bit of the prosecution history of the '539 patent Ms. Holland asked you about, I believe, is that correct?
A. That's correct. Page nine, I believe.
Q. All right. And she asked you, I think she asked you questions, would prosecution history have informed somebody of

skill in the art in 1994 about the meaning of approximately 6:2:5:1, is that correct?

A. She did ask me that, yes.

Q. Could we go to the last page of PTX-20A, please.

Dr. Kent, do you see a date on this document?

A. I do. And the date appears to be 12, is that '04 or '07? '04, I think.

Q. All right. At the risk of asking the obvious, would that document from December of 2004 have informed somebody of the skill in the art in 1994?

A. I'm sorry?

Q. That was a question for you. Sorry. At the risk of stating the obvious, would a document --

THE COURT: It is too obvious.

MR. ANSTAETT: Okay. I'll move on. Could I have just one second, your Honor?

THE COURT: Of course.

MR. ANSTAETT: I'm almost finished, your Honor.

Q. Let's look at PTX-20. And we can just use the original PTX-20. And if we go to page one with the Bates number 304802.

All right, I believe this is the prosecution history that Ms. Holland asked you about, if we could just highlight the bottom paragraph there, please. And here Teva is discussing three batches of copolymer-1 obtained from the Weizmann Institute. Do you see that, Doctor?

A. I do.
Q. The sentence? Okay. And do you see some -- oh, if we could keep that up, please. We'll get it back up. I think we lost the signal. All right, there we go.
And do you see that there's some batch numbers associated there with those Weizmann batches?
A. It says Weizmann batch numbers 320, 340 and 400.
Q. All right. And it is those batches that Teva has reported molar ratios there for, correct; the molar ratios at the bottom?
A. That --
Q. It's those batches 320, 340 and 400 that Teva has retested using total amino acid analysis and gotten those molar ratios, at the bottom?
A. That's what it says here, yes.
Q. All right. Now, the reported ratio for each of those batches has a tyrosine content of 1.0, is that correct?
A. That's correct. All three have tyrosine 1.0.
Q. All right. New, let's look at DTX-1704, please. And I want to turn to page TEV3004350, please. And if we could blow up everything that's under number three there, please.
Now, you see on the left-hand column there are a list of batch numbers?
A. Yes, WIS320, 340 and 400, I assume WI stands for Weizmann Institute of Science.

Q. Are those the same batch numbers that we just saw listed in the prosecution history?
A. The 320, 340 and 400 are the same, yes.
Q. All right. Now, the final column in this chart, what does that reflect there?
A. Here they've done amino acid analysis that includes a separate test for the determining the bromotyrosine content.
Q. All right. And then I want to ask you if you'll read the, where it says table three right under the table. That's rather small.
A. Yes. So what it says there is table three, amino acid content of BR1 batches. Since the tyrosine content was significantly lower than expected, an HPLC determination of the contents of brominated tyrosine, Br-Tyr, residues was also performed.
Q. All right. And then let me ask you this. Do you see the bottom row?
A. Yes, I do.
Q. And if you would read the sentence top of the table that starts with table three?
A. I'm sorry, I'm not sure -- oh, up the top?
Q. Yes, please.
A. Yeah. Table three presents the results of analysis in comparison to Teva's current specifications, and those of the reference standard batch, 03494, which is the one at the bottom

of the table.
Q. All right. Now, do you see the molar fraction for tyrosine in the Teva reference batch there at the bottom of the table?
A. I do. It's in the Teva reference. It's 0.095 for the molar fraction of tyrosine.
Q. And what is that report in terms of bromotyrosine in the Teva reference batch, if we look the final column?
A. It reports it as less than 0.2 percent.
Q. And what about for the Weizmann batches, what was the report of the bromotyrosine content for the Weizmann batches?
A. Reported respectively as 1.12 percent, 1.09 percent and 1.23 percent.
Q. All right, now, I'm almost done, Dr. Kent. We've got molar fractions in this table, correct, for each of the three Weizmann batches?
A. For glutamic acid, alanine, tyrosine and lysine we have molar fractions. For bromotyrosine we have a percent.
Q. All right. And focusing on the molar fractions for glutamic acid, alanine, tyrosine and lysine, using those molar fractions, could we calculate molar ratios from those fractions?
A. Yes, we could, for the three Weizmann batches and for the Teva standard batch.
Q. All right. Now, I'm going to -- I'm going to ask you to briefly do just a little math for me and I'll bring you a

calculator. And what I want you to do is using the Weizmann Institute 320 batch --

A. Yeah.

Q. -- I'd like you to calculate a molar ratio for that batch normalized to tyrosine?

A. All right. So the tyrosine mole fraction is .078. So we divide all four numbers in the highlighted top row by .078. So we'll start with .145 divided by .078 equals 1.86, 1.858, 1.86.

Q. All right. And 1.86 if we're looking at two significant figures it would 1.9?

A. Yes, that would be 1.9.

Q. All right.

A. So for alanine -- figure out how to clear this thing -- there. .468 divided by .078, and that's six point as many zeros as you want.

Q. So can we call that 6.0?

A. Yes.

Q. All right.

A. So tyrosine obviously is 1.0.

Q. Right.

A. And for lysine .312 divided by .078 equals 4.0.

Q. All right, 4.0. Now, if we could go back please to the '539 prosecution history page we were looking at before. It is PTX-20 at 304802.

And, Nick, if could you highlight the molar ratios at

the bottom of the page, please.

I think we established earlier that starting at 1.9 down there.

I think we established earlier that that was one of the Weizmann batches, the batch number 320?

A. Yes.

Q. All right. And did we just calculate a molar ratio for that batch based on the molar fractions reported for that batch?

A. We did.

Q. And did we just come up with a molar ratio of 1.9 to 4.0 to 6.0 to 1.0?

A. We did.

Q. And was that molar ratio normalized to tyrosine?

A. In the conventional sense of normalized. All ratios are with respect to tyrosine, which is reported as 1.0.

Q. So when Teva wanted to compare batches of copolymer-1 and tell the patent office about them, they calculated molar ratios normalized to tyrosine; is that fair to say?

A. They did.

MR. ANSTAETT: Nothing further.

THE COURT: All right. Is there anything else?

MS. HOLLAND: No, your Honor.

THE COURT: All right, thank, you Dr. Kent. You may step down.

(Witness excused)

THE WITNESS: Thank you.

THE COURT: Mr. Skilton?

MR. SKILTON: Yes, your Honor. Our next witness is about two and a half to three hours, so I'll leave it to the Court's discretion as to whether you would like us to start or call the witness or go home.

THE COURT: Why don't we get started, take few minutes.

MR. SKILTON: Your Honor, the Mylan defendants call Doctor Allen Zeiger.

ALLEN ZEIGER,

called as a witness by the defendant,

having been affirmed, testified as follows:

DIRECT EXAMINATION

BY MR. SKILTON:

MR. SKILTON: Your Honor, can we have a moment to hand out the binders?

THE COURT: Yeah, sure.

MR. SKILTON: Your Honor, would it be okay for my colleague Melony Glaser to sit in the jury?

THE COURT: Sure, that would be fine.

MR. SKILTON: She can evaluate my performance that way.

Q. Would you please state your full name for the record?

A. Allen Zeiger.
Q. Are you currently employed?
A. No. I'm retired.
Q. You're retired. When did you retire?
A. In 2008.
Q. Where did you retire from?
A. I retired from Jefferson Medical College Thomas Jefferson University in Philadelphia.
Q. What position did you hold at Jefferson Medical College, on your retirement?
A. On my retirement, I was a professor of biochemistry and molecular biology.
Q. Where do you live, Dr. Zieger?
A. I live part-time in Silver Spring, Maryland and part-time in Beth Shemes, Israel.
Q. Doctor, have you ever testified before in court?
A. No.
Q. Are you familiar with a composition called copolymer-1?
A. Yes, I am.
Q. And how so?
A. I've been asked by Perkins Coie to review the copolymer-1 patents, particularly the '550, '808 and the patents in suit, and to render opinions on matters in the patent in the literature and on obviousness in the various claims.
Q. All right. Now, you have, I would assume, a C.V?

A. I do.
Q. And, Nick, would you kindly pull up DTX-1966. That should be in your book as such?
A. It is.
Q. Doctor?
A. I am.
Q. Would you identify this document, please, for the Court, if you get it?
A. This. This is my CV, yes.
Q. And is it accurate, to the best of your knowledge?
A. Yes, it is.
MR. SKILTON: Your Honor, I move into evidence DTX-1966.
MR. JAMES: No objection.
THE COURT: Admitted.
(Defendant's Exhibit DTX-1966 received in evidence)
Q. Thank you, your Honor.
I would now ask you to turn to some slides I think that are essentially summaries of portions of that.
And, Nick, if you could pull up slide one of Doctor -- all right.
Doctor, I'll represent to you that this is a summary of some aspects of your C.V. And would you take the Court through that slide in terms of, particularly focusing on your experience as it relates to the matters that you'll be talking

about today and tomorrow, and let's start with your Ph.D.?
A. My Ph.D. was in biology in the McCallum Pratt Institute of Biochemistry in Baltimore Maryland, which I received a 1967. The thesis focus was on the interactions of cancer causing chemicals with DNA the genetic material.
Q. Let me stop you right there. That's a mouth full. How does that experience relate, if at all, to the kinds of issues you're going to be talking about?
A. Well, the nucleic acid is a polymer with a great degree of charge and the particular kind of DNA I was looking at was poly disperse. In that respect, I was looking at some of their hydrogenatic properties, and the interactions with these chemicals with biological activity.
Q. And you successfully obtained that Ph.D.?
A. Yes, I did.
Q. And where did you go after that?
A. From there I became a post doctoral student at National Institutes of Health in the laboratory of Christian B. Anfinsen for a two year period.
Q. And who was Dr. Anfinsen at that time?
A. Dr. Anfinsen was a world renowned protein chemist who received the Nobel Prize in chemistry in 1972.
Q. Now, describe, would you, please, the nature of the work that you did during this post doc two year period at NIH?
A. At this time Dr. Anfinsen's lab was focused on the

activity, the mechanism of action of an enzyme that broke down nucleic acid materials, in this case RAN, and this enzyme was able to be cleaved by another enzyme into three fragments. I was asked to do a solution peptide synthesis of one of these three fragments.

Q. Can you translate that to work, at least roughly into the kind of chemistry biochemistry that you're analyzing for the Court in the next few days?

A. Yes. I was extensively involved in peptide synthesis, and this included such as areas as protection which we've heard about, and deprotection and step-by-step characterization and purification of protected peptide intermediates.

Q. And as to the molecules or the composition, how does that compare, for example, copolymer-1?

A. Well, these were more related to the building blocks because at this point in my career I was mainly concerned with synthesizing peptides that were although long peptides, not polypeptides.

Q. I'll get into your definitions of some of these terms a little later, but take us, then, to your next employment as per the resume. You next were at the Jefferson Medical College?

A. Yes. I joined the Biochemistry Department of Jefferson Medical College, Thomas Jefferson University, in Philadelphia, in 1969, as assistant professor. I was asked to use my background in peptide chemistry to study the means of

recognition of the immune system of polypeptides, both random polypeptides as well as polypeptides of known sequence. In particular, I was asked to develop methods of synthesis of peptides, polypeptides of known sequence.

Q. And again I'm going to return you to the subject of relating that work to the kind of analysis and opinions that you're developing in this case.

A. I understand.

Q. And what is the relationship, how would you describe it?

A. Well, the random polypeptides are very much like the copolymer-1 gamish, if I may use a mixture, in the sense that they were poly disperse, they were often times charged, and they were composed of many of the same amino acids that are found in copolymer-1.

Q. And you remained as assistant professor from 1969 to '76?

A. I did.

Q. Dr. Zeiger, describe up to '76, I'm going to say your laboratory work, white coat work that you did up to that time?

A. We were interested in the way elements of the immune system would recognize peptides, in particularly we wanted to remove one the variables of the polypeptides that were used up to then, namely, the random sequence, and consequently we used those of random sequence as a model system to compare with the sequences of known sequence that we prepared.

Q. Okay. And we'll return I think on occasion to this portion

of your career, but take us then to the next step along the way; associate professor 1976 through 1984?
A. Well, very much the way -- I'm sorry -- the way that Michael Sela and Ruth Arnon took their polypeptide work towards multiple sclerosis, I began to take my work more towards the bacterial cell wall envelope, which I thought I still feel was the battle ground between a pathogen and the host.
Q. And one of the bullet points here, I'm going to get to the full professor in a moment, but one of the bullet points describes the research focus on synthesis and characterization. Would you fill in a little bit what is there described in terms of your research and your work?
A. Yes. I was interested in developing methods for the synthesis of polypeptides of known sequence of high molecular weight that were to be used as immunogens in laboratory animals, rabbits, guinea pigs, mice, in order to study the way that their sequence and their hydrodynamic properties interrelate with immune recognition both at the molecular level, meaning anti-bodies and also at the genetic level.
Q. All right. Now, let's focus on the immune recognition of your last answer. Were you looking at immunological properties during this period and, if so, in what context?
A. In context of cross reactions, as one example. In context with genetic control of the immune response as another example.
Q. Were you working with amino acids?

A. Yes, I was.
Q. And would you describe that, please?
A. Well, if you take a look at some of the references, the bibliography, you'll see the use of peptide synthesis, in the production of peptides of known sequence, as well as their characterization. And also you'll see some papers in which we used random polymers containing such amino acids as glutamic acid, lysine, tyrosine and alanine.
Q. And you named those amino acids. Are those common to the copolymer-1 molecule?
A. They are.
Q. And were there molecular weights or rate molecular weight ranges that you were working on during this period?
A. Especially of interest to me was the molecular weight ranges of the polypeptides that I synthesized of known sequence.
Q. And give the Court a little sense of what you mean when you said that you synthesized, how it relates to that the synthesis that we've been hearing about so far of copolymer-1?
A. This, the specifics of the synthesis, there are a number of aspects of the synthesis of the polypeptides which were in common with the synthesis of copolymer-1, such as the need to protect certain groups and the need to then deprotect them in order to study them.
Q. All right. And you're describing work then that you did in

the lab during this period that we've just covered, correct?
A. I am.
Q. All right. Now, let's go, if we could, to slide two, another summary slide relating to your C.V. And why don't you go down the bullet points as therein stated?
A. I was the author of more than 40 research articles, the sole inventor on three patents. I've been a member of a number of professional societies, including an elected member of the American Society of immunologists, and an elected member of the American Society of Biological Chemists, but in addition I've been a member at some period of the American Peptide Society and the American Society for microbiology.
Q. And you'll note that we've pulled out of your resume two sabbaticals. Would you describe those sabbaticals for the Court and how, if at all, they relate to some of the inventors in this case?
A. I spent two sabbaticals, two years at the Weizmann Institute of Science in Rehovot, Israel in the biophysics department, which is where both doctors Arnon and Sela started off. The first time was with Dr. David Mirelman, who was an expert in the bacterial cell wall. I was just beginning to get involved in that, and in a big way, and I looked to him as somebody who would take me from a person of perhaps a little bit more than ordinary skill to an expert, somebody with expertise.

The second sabbatical in the same department was with Doctor Mayer Wilchek, who is a world renowned authority on chromatography. He's published over 500 papers, I believe, and has over 100,000 citations to those papers.

Q. I'm going to return here just for a minute then to the synthesis work that you were doing on polypeptides as you described. Was there an ultimate goal of that work that you were doing in the lab?

A. Yes. The ultimate goal was to try to eliminate as much as possible the variability of amino acid sequence, however, the variability of poly dispersity remained.

Q. Now, you've been in the courtroom, and I know you've studied the work of Doctors Arnon and Sela. How would you compare the work you were doing during this period with the work that you knew of the scientists Doctor Arnon and Sela, during this period?

A. The group at Jefferson that I was working with were interested in the same sorts of questions that Doctors Sela and Arnon were interested in, in terms of utilizing these random polypeptides as models for studying the finer points of the immune system.

Q. Would you return to slide one and let's complete the resume, chronologically. Have we covered, more or less, the period of associate professor in terms of relevant activities to the issues you're studying?

A. Yes.
Q. Then you became a full professor in 1984 and remained as such according to this, until you retired in 2008. How would you relate that period to the work that you're doing at the request of Perkins Coie in this case?
A. Just as Dr. Sela and Arnon, although they didn't completely leave the previous studies, just as they moved into an area of great medical relevance and excitement such as multiple sclerosis, I moved more into the area of the bacterial cell wall and the effects of antibiotics on the bacterial cell wall.
Q. And you mentioned it was simultaneously, your lab was working simultaneously with the work that was being done by their lab?
A. Yes.
Q. Did Dr. Sela at any time ever recognize your work in any article that he published?
A. Yes, he did.
Q. And, Nick, would you pull up DTX-1901, please.
Do you have 1901 in your collection of documents?
A. I'm looking at it on the screen.
Q. All right. Well, let me first ask you to identify it for the record. What is the Court looking at now?
A. This is a review article that Michael Sela published, in the federation of European Biological Society Letters, and in March of 1974.

Q. And were you able at sometime thereafter to read this article?
A. Yes, I was very interested in it, and the title has selected highlights in immunological research in the last decade.
Q. And was it published in a reputable publication?
A. Yes.
MR. SKILTON: Your Honor, I move into evidence DTX-1901.
MR. JAMES: No objection.
THE COURT: All right. Admitted.
(Defendant's Exhibit 1901 received in evidence)
Q. And would you take a minute, Dr. Zeiger, and point the Court to those portions of that article that refer to your work?
A. Yes, Nick, could you please --
Q. Why don't we return to S90 in terms of getting that reference point here.
Dr. Zeiger, what is this paragraph in this article referring to?
A. I believe that Nick pulled off -- pulled up the wrong paragraph.
Q. That was my fault.
A. If you look at the second paragraph, yes, that one over there. I don't seem to have a laser pointer, which --

MR. SKILTON: Which would be helpful.

Q. We'll get one for you tomorrow. What are you pointing out to the Court here?

A. The paragraph is discussing cross reactivity between totally synthetic materials and biological materials, and in particular, if I may read the first sentence. There synthetic antigens have been described capable of provoking anti-bodies cross reacting with a bacterial cell wall, and with a basic protein of the myelin sheath, such polymers may suppress the permittal disease allergic encephamyilitis, and there are two references there. It also mentions collagen.

Q. And the references to the first clause 118, are you aware of what that reference is?

A. Yes. That's to my work.

Q. And 119 and 120?

A. That's a reference to the work that we've been discussing dealing with copolymer-1.

Q. And, Nick, would you pull up 118 and 119, and 120. All right. And 118 says Zeiger, 119 is Teitelbaum, and 120 is Teitelbaum, et al. Am I reading that correctly?

A. It is the way Cynthia Web and -- who is, I believe, a post -- I'm sorry -- a graduate student at that time.

Q. And as you read that, why are these three articles mentioned, if you will, in the same sentence?

A. Well, they're mentioned as selected highlights. This was a

period of time in chemistry in which chemists and biochemists were making an attempt to kind of fool mother nature by taking something, making something totally synthetically chemically in a test tube and injecting animals with the hope that the anti-bodies and cells that are elicited that are provoked from this, these immunizations would be able to cross react with natural materials.

Q. And did Dr. Sela, more or less, state his purpose as you understood it, in this article?

A. His purpose was to try to mimic the reaction to the myelin basic sheath.

Q. What did you understand?

A. I'm sorry.

Q. I'm sorry?

A. The myelin basic sheath protein.

Q. All right. And what did you understand his purpose was in writing this article?

A. To highlight those areas of greatest potential and greatest interest in the field at that time.

Q. And, Nick, would you pull up S.85, please. And does he state that purpose, as you understood it in the first sentence of the article?

A. Yes, he does. Could I read it?

Q. Please.

A. This is an impressionistic and therefore undoubtedly

subjective view of one immunologist on what seemed to him is most interesting developments in the broad realm of immunology in the last ten years.

Q. Doctor, do you consider yourself to be an expert in the field of biochemistry?

A. I do.

Q. First of all, tell me what immuno chemistry is because then I am going to ask you whether you think you're an expert in it?

A. Immuno chemistry is a study of recognition by different materials or systems in the immune system of both foreign and native materials in a host.

Q. And do you consider yourself to be an expert in this area?

A. I do.

Q. And this case relates to peptides and polymers. Do you consider yourself to be an expert in synthetic peptide chemistry?

A. I do.

Q. Do you consider yourself to be an expert in peptide polymer chemistry?

A. Yes, I do.

Q. Do you consider yourself an expert in the characterization of the properties of peptide polymers?

A. Yes, I do.

MR. SKILTON: Your Honor, I tender Dr. Zeiger as an expert on all of those topics.

MR. JAMES: Your Honor, we have no objection. I'm not sure I understand the last parts about characterization of peptide polymers, but with that caveat, no objection.

THE COURT: Okay. Well, I -- do you want to go into what you mean by characterization of peptide polymers?

MR. SKILTON: Yes, your Honor, I will.

THE COURT: Obviously, I accept Dr. Zeiger with respect to the first four categories.

MR. SKILTON: Thank you, your Honor.

Q. Would you explain to the Court what you mean to convey when you state that you consider yourself to be an expert in the characterization of the properties of peptide polymers?

A. Yes, I, in the publications that I published, among other things I have used ultracentrifugation, I've used viscosity, and I've used circular dichroism as a means of studying both poly dispersity, molecular weight ranges, and the -- well, I'll stick with those. The -- and also possible secondary structures of these polymers.

Q. And this relates to work you've done in the lab?

A. Yes.

Q. And professional articles that you've written?

A. Yes, as well as teaching many of these areas in the, to graduate students and to medical students.

MR. JAMES: Your Honor, I didn't hear any mention of size exclusion chromatography. So long as we're not agreeing

that he is being admitted as an expert on size exclusion chromatography, we don't have an objection.

MR. SKILTON: Your Honor, may I ask the witness --

THE COURT: Is there going to be any expert testimony on size exclusion chromatography?

MR. SKILTON: My belief is that that subject will come up in his testimony. I'm not sure that any of the it will be tendered as an expert, but since issue is raised at least I like to have him give the Court his background.

THE COURT: Why don't we do that when the testimony about SEC comes up.

MR. SKILTON: Thank you, your Honor.

THE COURT: Give us a warning and then we can --

MR. SKILTON: Will do.

THE COURT: We can have a voir dire with respect to that, okay, if that's requested.

MR. SKILTON: Thank you.

THE COURT: And now I'm going to adjourn, Mr. Skilton. Thank you for beginning. Dr. Zeiger, thanks for starting out this evening. See everybody at 9:30 in the morning.

MR. SKILTON: Thank you, your Honor.

MR. JAMES: Thank you.

(Adjourned to September 14th, 2011 at 9:30 a.m.)

INDEX OF EXAMINATION

PLAINTIFF EXHIBITS

DEFENDANT EXHIBITS

Exhibit No.	Received
1270	689
1901	795
1963	651
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DTX 1271	686
DTX 1411	643
DTX 1925	694
DTX 52T	682
DTX-1966	786